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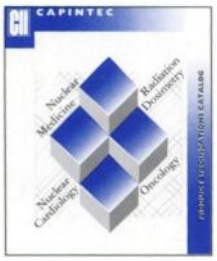

Please see us at the SNM Annual Meeting. Island #501

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42 ANNUAL MEETING

MINNEAPOLIS

Join more than 8000 of your colleagues in celebrating the 42nd Annual Meeting of the Society of Nuclear Medicine in Minneapolis Minnesota, June 11-15, 1995. Participate in the intensive educational program, review posters, discuss the most recent developments with colleagues, and join any of a host of much talked about extracurricular activities. Don't miss this opportunity to learn, mingle with your colleagues, and visit with exhibitors.

Refresher and state-of-the art continuing education courses in chemistry, physics, quality assurance, cardiovascular nuclear medicine, PET, SPECT and NMR will supply up-to-the-minute approaches and procedures for all clinical settings.

SCIENTIFIC PAPERS

This years presentation of over 1000 scientific papers and posters includes a distillation of the latest advancements and finest work achieved by outstanding scientists and physicians in the field of nuclear medicine. These papers, presented by the original authors, with over 30 subjects to choose from, will provide a unique opportunity for enhancing your knowledge or exploring new avenues in correlative areas of nuclear medicine. Ample time is allotted at these presentations for questions and discussions. An extensive display of scientific posters and exhibits will augment the presentation. The ever-increasing importance of the role of the nuclear medicine technologist will be explored in our Technologist Program, with over 70 hours of clinical updates will provide chief and staff technologists with the latest in basic, intermediate, and advanced studies. This program will broaden expertise and enhance the technologist's contribution to nuclear medicine.

AUDIOVISUALS, BOOKS, JOURNALS

The Society of Nuclear Medicine is continuously adding to its library of audiovisuals, books, and other publications. A stop at the publications booth is well worth the time. Here you will find on display what the Society has to offer for year-round educational advancement. Networking opportunities and job referral boards are available at special locations throughout the meeting as well as membership information at our membership booth.

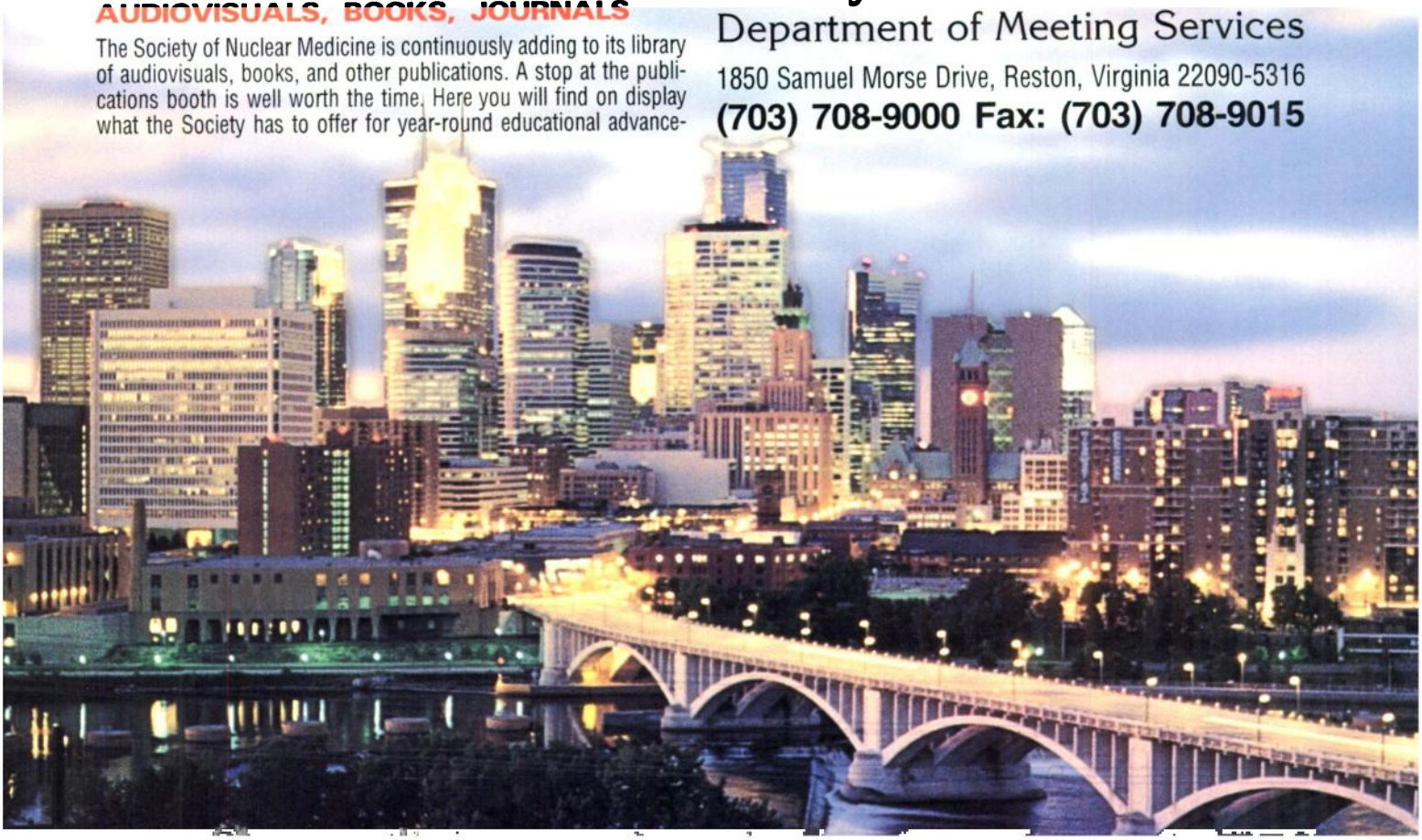
EXHIBIT

All the major manufacturers of nuclear medicine products and services-more than 100 in all-will be on hand to explain and demonstrate the most technologically-advanced equipment. Several companies will present User Meetings to give an in-depth understanding of their products.

	Before May 5	After May 5
Physicians/Scientists		
Members	$180.00	$200.00
Nonmembers	$275.00	$295.00
Technologists		
Members	$150.00	$170.00
Nonmembers	$275.00	$295.00

If you need further information, please contact:

Society of Nuclear Medicine
Department of Meeting Services
1850 Samuel Morse Drive, Reston, Virginia 22090-5316
(703) 708-9000 Fax: (703) 708-9015



STEP.™ A thousand clinical cases later.

"We do perform 360-degree rotation with STEP and we feel that the additional data acquired is very helpful."

Stuart Gottlieb, M.D., Mercy Outpatient Center, Nuclear Cardiology Laboratory, Miami, FL.

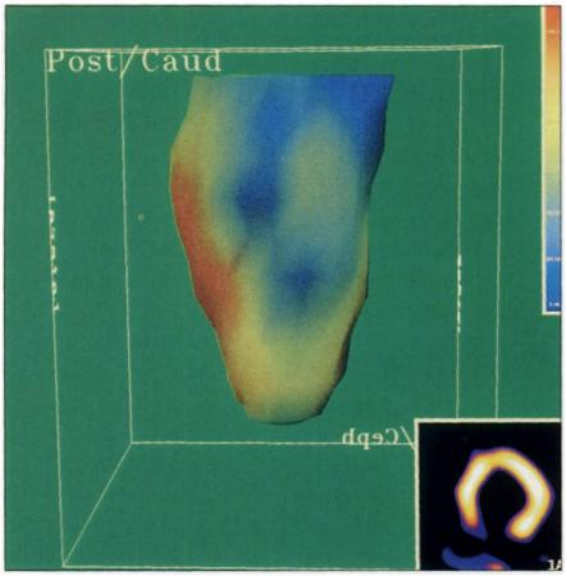
"The STEP technique has had a significant effect on the accuracy of our diagnosis in our laboratory..."

Fred Datz, M.D., Professor of Radiology, Director of Nuclear Medicine, University of Utah School of Medicine, Salt Lake City, UT.

"Our preliminary comparison of STEP with standard imaging and cardiac catheterization in over 300 patients suggests that STEP appropriately eliminates attenuation artifacts."

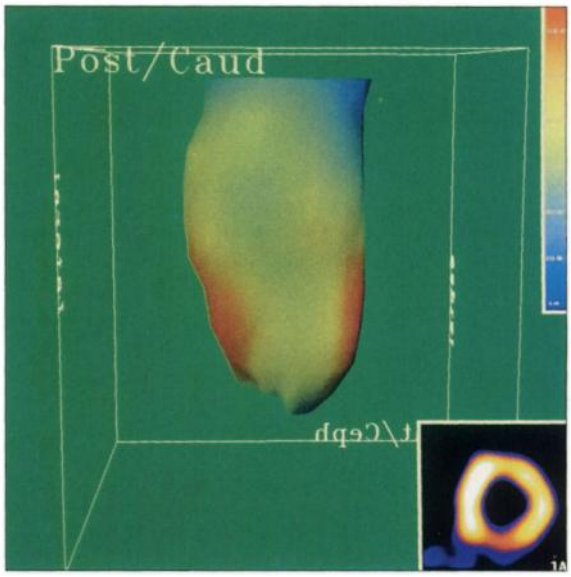
Timothy Blackburn, M.D., Research Medical Center, Kansas City, MO.

Blue area in 3-D rendered conventional thallium image represents decreased activity in the inferior wall due to diaphragmatic attenuation. (Also seen in short axis slice.)



Conventional SPECT.

STEP eliminates artifact, clearly showing normal perfusion in the inferior wall area of 3-D rendered STEP image. (Also seen in short axis slice.)



STEP

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Simultaneous transmission Emission Protocol (STEP) was also the first commercially available non-uniform attenuation correction device for 360-degree cardiac SPECT. This leading-edge technology is just another one of those industry firsts you've come to expect from us. For clinical proof, call Picker today at 1-800-323-0550. Picker International, 595 Miner Road, Cleveland, Ohio 44143.

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It's not over until you get past the artifacts

When female and large-chested or obese male patients undergo myocardial perfusion imaging, there is the potential for images to be peppered with artifacts—possibly resulting in inconclusive studies.

Cardiolite® comes through, especially in these patients. The higher photon energy (140 keV) provides greater anatomical detail to enhance interpretive confidence—which may reduce false-positives and equivocal cases.

Cardiolite also offers the unique advantage of direct measurement of both myocardial perfusion and ventricular function from one study.

So rather than settle for potentially inconclusive images, use Cardiolite and reduce soft-tissue attenuation.

Please see us at the SNM Annual Meeting. Island #909

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

To reduce soft-tissue attenuation Cardiolite comes through

DU PONT
PHARMA
Radiopharmaceuticals

Stress testing should be performed only under the supervision of a qualified physician in a laboratory equipped with appropriate resuscitation and support apparatus. There have been infrequent reports of signs and symptoms consistent with seizure and severe hypersensitivity after administration of Tc99m Sestamibi.

Please see brief summary of prescribing information on adjacent page.

Brief Summary

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

FOR DIAGNOSTIC USE

DESCRIPTION: Each 5ml vial contains a sterile, non-pyrogenic, lyophilized mixture of:
Tetrakis (2-methoxy isobutyl isonitrile) Copper (I) tetrafluoroborate - 1.0mg
Sodium Citrate Dihydrate - 2.6mg
L-Cysteine Hydrochloride Monohydrate - 1.0mg
Mannitol - 20mg
Stannous Chloride, Dihydrate, minimum ($SnCl_2 \cdot 2H_2O$) - 0.025mg
Stannous Chloride, Dihydrate, ($SnCl_2 \cdot 2H_2O$) - 0.075mg
Tin Chloride (Stannous and Stannic) Dihydrate, maximum (as $SnCl_2 \cdot 2H_2O$) - 0.086mg

Prior to lyophilization the pH is 5.3-5.9. The contents of the vial are lyophilized and stored under nitrogen.

This drug is administered by intravenous injection for diagnostic use after reconstitution with sterile, non-pyrogenic, oxidant-free Sodium Pertechnetate Tc99m Injection.The pH of the reconstituted product is 5.5 (5.0-6.0). No bacteriostatic preservative is present.

The precise structure of the technetium complex is $Tc99m[MIBI]_6^+$ where MIBI is 2-methoxy isobutyl isonitrile.

INDICATIONS AND USAGE: CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is a myocardial perfusion agent that is useful in the evaluation of ischemic heart disease. CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is useful in distinguishing normal from abnormal myocardium and in the localization of the abnormality, in patients with suspected myocardial infarction, ischemic heart disease or coronary artery disease. Evaluation of ischemic heart disease or coronary artery disease is accomplished using rest and stress techniques.

CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is also useful in the evaluation of myocardial function using the first pass technique.

Rest-exercise imaging with Tc99m Sestamibi in conjunction with other diagnostic information may be used to evaluate ischemic heart disease and its localization.

In clinical trials, using a template consisting of the anterior wall, inferior-posterior wall and isolated apex, localization in the anterior or inferior-posterior wall in patients with suspected angina pectoris or coronary artery disease was shown. Disease localization isolated to the apex has not been established. Tc99m Sestamibi has not been studied or evaluated in other cardiac diseases.

It is usually not possible to differentiate recent from old myocardial infarction or to differentiate recent myocardial infarction from ischemia.

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, care should be taken to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedure. Infrequently, death has occurred 4 to 24 hours after Tc99m Sestamibi use and is usually associated with exercise stress testing (See Precautions).

PRECAUTIONS:

GENERAL

The contents of the vial are intended only for use in the preparation of Technetium Tc99m Sestamibi and are not to be administered directly to the patient without first undergoing the preparative procedure.

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

Contents of the kit before preparation are not radioactive. However, after the Sodium Pertechnetate Tc99m Injection is added, adequate shielding of the final preparation must be maintained.

The components of the kit are sterile and non-pyrogenic. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Technetium Tc99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, Sodium Pertechnetate Tc99m Injection containing oxidants should not be used.

Technetium Tc99m Sestamibi should not be used more than six hours after preparation.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

The most frequent exercise stress test endpoints, which resulted in termination of the test during controlled Tc99m Sestamibi studies (two-thirds were cardiac patients) were:

Fatigue	35%
Dyspnea	17%
Chest Pain	16%
ST-depression	7%
Arrhythmia	1%

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5rads/30mCi at rest, 1.2 rads/30mCi at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section.)

The active intermediate, $[Cu(MIBI)_4]BF_4$, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all *in vitro*). At cytotoxic concentrations (≥ 20μg/ml), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. $[Cu(MIBI)_4]BF_4$ did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9mg/kg, > 600 × maximal human dose).

Pregnancy Category C

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Sestamibi. It is also not known whether Technetium Tc99m Sestamibi can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc99m Sestamibi should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Technetium Tc99m Pertechnetate is excreted in human milk during lactation. It is not known whether Technetium Tc99m Sestamibi is excreted in human milk. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

Safety and effectiveness in children below the age of 18 have not been established.

ADVERSE REACTIONS: During clinical trials, approximately 8% of patients experienced a transient parosmia and/or taste perversion (metallic or bitter taste) immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing, edema, injection site inflammation, dyspepsia, nausea, vomiting, pruritus, rash, urticaria, dry mouth, fever, dizziness, fatigue, dyspnea, and hypotension also have been attributed to administration of the agent. Cases of angina, chest pain, and death have occurred (see Warnings and Precautions). The following adverse reactions have been rarely reported: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient arthritis in a wrist joint; and severe hypersensitivity, which was characterized by dyspnea, hypotension, bradycardia, asthenia and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

DOSAGE AND ADMINISTRATION: The suggested dose range for I.V. administration in a single dose to be employed in the average patient (70kg) is:

370-1110MBq (10-30mCi)

The dose administered should be the lowest required to provide an adequate study consistent with ALARA principles (see also PRECAUTIONS).

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to patient administration. Radiochemical purity should be checked prior to patient administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Store at 15-25°C before and after reconstitution.

RADIATION DOSIMETRY: The radiation doses to organs and tissues of an average patient (70kg) per 1110MBq (30mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 4.

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

	Estimated Radiation Absorbed Dose			
	REST			
	2.0 hour void		4.8 hour void	
Organ	rads/ 30mCi	mGy/ 1110MBq	rads/ 30mCi	mGy/ 1110MBq
Breasts	0.2	2.0	0.2	1.9
Gallbladder Wall	2.0	20.0	2.0	20.0
Small Intestine	3.0	30.0	3.0	30.0
Upper Large Intestine Wall	5.4	55.5	5.4	55.5
Lower Large Intestine Wall	3.9	40.0	4.2	41.1
Stomach Wall	0.6	6.1	0.6	5.8
Heart Wall	0.5	5.1	0.5	4.9
Kidneys	2.0	20.0	2.0	20.0
Liver	0.6	5.8	0.6	5.7
Lungs	0.3	2.8	0.3	2.7
Bone Surfaces	0.7	6.8	0.7	6.4
Thyroid	0.7	7.0	0.7	6.8
Ovaries	1.5	15.5	1.6	15.5
Testes	0.3	3.4	0.4	3.9
Red Marrow	0.5	5.1	0.5	5.0
Urinary Bladder Wall	2.0	20.0	4.2	41.1
Total Body	0.5	4.8	0.5	4.8
	STRESS			
	2.0 hour void		4.8 hour void	
Organ	rads/ 30mCi	mGy/ 1110MBq	rads/ 30mCi	mGy/ 1110MBq
Breasts	0.2	2.0	0.2	1.8
Gallbladder Wall	2.8	28.9	2.8	27.8
Small Intestine	2.4	24.4	2.4	24.4
Upper Large Intestine Wall	4.5	44.4	4.5	44.4
Lower Large Intestine Wall	3.3	32.2	3.3	32.2
Stomach Wall	0.5	5.3	0.5	5.2
Heart Wall	0.5	5.6	0.5	5.3
Kidneys	1.7	16.7	1.7	16.7
Liver	0.4	4.2	0.4	4.1
Lungs	0.3	2.6	0.2	2.4
Bone Surfaces	0.6	6.2	0.6	6.0
Thyroid	0.3	2.7	0.2	2.4
Ovaries	1.2	12.2	1.3	13.3
Testes	0.3	3.1	0.3	3.4
Red Marrow	0.5	4.6	0.5	4.4
Urinary Bladder Wall	1.5	15.5	3.0	30.0
Total Body	0.4	4.2	0.4	4.2

Radiopharmaceutical Internal Dose Information Center, July, 1990, Oak Ridge Associated Universities, P.O. Box 117, Oak Ridge, TN 37831, (615) 576-3449.

HOW SUPPLIED: Du Pont Radiopharmaceuticals' CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is supplied as a 5ml vial in kits of two (2), five (5) and thirty (30) vials, sterile and non-pyrogenic.

Prior to lyophilization the pH is between 5.3-5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at 15-25°C before and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives. Included in each two (2) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each five (5) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each thirty (30) vial kit are one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

The U.S. Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material pursuant to section 35.11 and section 35.200 of Title 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

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Radiopharmaceuticals

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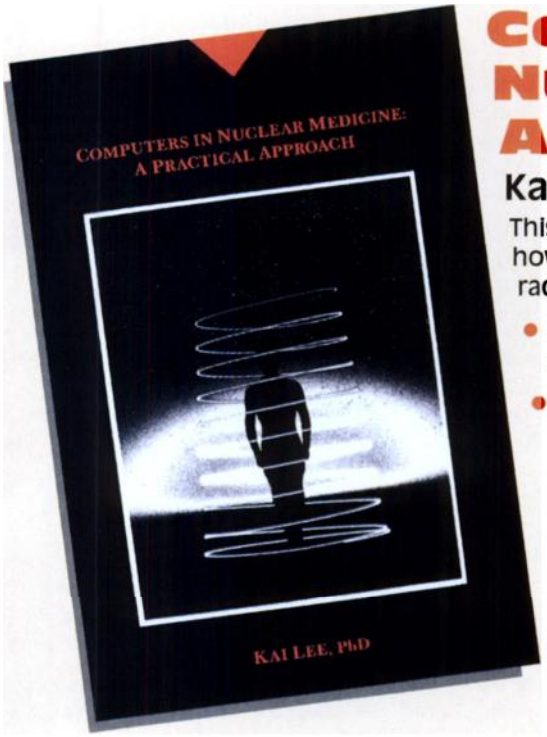
The Du Pont Merck Pharmaceutical Co.
331 Treble Cove Road
Billerica, Massachusetts, USA 01862

513121-0394
Brief Summary

3/94 Printed in U.S.A.

Computer Friendly...

These recent SNM books are your best guides to mastering nuclear medicine computer technology. From basic systems to Fourier transformations, you'll find what you need to stay in front of this rapidly changing field.



Computers in Nuclear Medicine: A Practical Approach

Kai Lee, PhD

This illustrated guide explains both how computers work and how processing techniques obtain diagnostic information from radionuclide images. Coverage includes:

- Hardware components in nuclear medicine computer systems. Principles behind common image processing techniques.
- How nuclear cardiology and SPECT highlight the interaction of hardward and software in nuclear medicine.

$30 MEMBERS
$42 NONMEMBERS

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Katherine Rowell, MS, CNMT, Editor

A companion text to *Computers in Nuclear Medicine*, this survey traces the evolution of nuclear medicine computer technology. Featured chapters describe how nuclear medicine study protocols have been radically altered through the use of computers; the revolutionary impact of computers on quality assurance; and the development of software and hardware for the gamma camera. An essential guide for staff operating computers in clinical settings.

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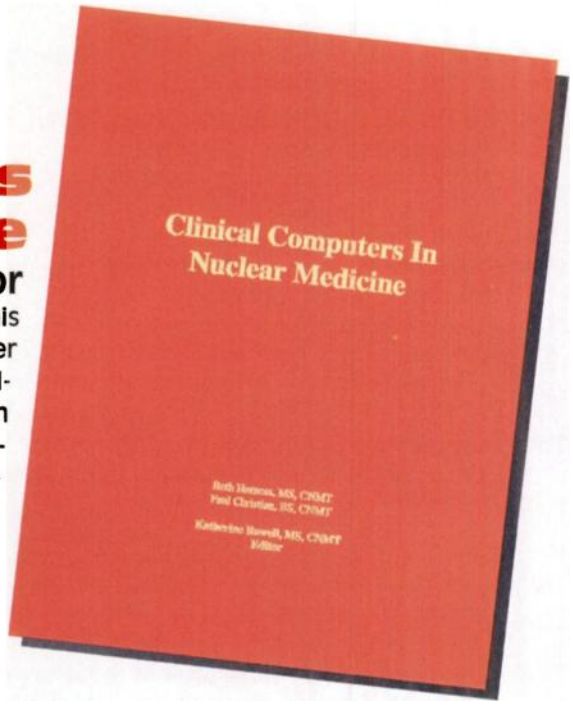

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Innovative design filed with the U.S. Patent and Trademark Office, patent pending.

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METASTRON®
(STRONTIUM-89 CHLORIDE INJECTION)

Simultaneously targets all sites of metastatic bone pain.

LONG-TERM PALLIATION IN ONE CONVENIENT DOSE.

- Palliation of pain demonstrated in the majority of patients.[1,2]
- One dose of Metastron provides pain relief for an average of up to 6 months.[1]
- As an adjunct to radiotherapy, 63.6% of patients receiving Metastron (10.8 mCi) had reduced pain at 6 months as compared to 35.0% of patients receiving placebo (n=42).[3]
- Preferentially incorporates into multiple sites of metastatic bone — the dose absorbed in metastatic deposits is approximately ten times that absorbed in normal bone marrow.[4,5]

ADJUNCTIVELY DELAYS THE MEDIAN TIME TO PROGRESSION OF PAIN BY 28.1 WEEKS OVER RADIOTHERAPY ALONE.

Median time to requirement for additional radiotherapy at new pain site.[3]

From a multicenter, double-blind study of 126 patients who received a single injection of either Metastron 400 MBq, 10.8 mCi or placebo with fractionated doses of local field radiotherapy (20-30 Gy).

HIGHLY EFFECTIVE NON-NARCOTIC THERAPY.

- Metastron may reduce or eliminate the need for dose escalation of narcotic analgesics.[1,3]
- Onset of pain relief is generally within 7 to 20 days—Metastron is therefore not recommended in patients with very short life expectancy.

GENERALLY WELL TOLERATED.

- A depression of white blood cell (20%) and platelet (30%) levels may occur in patients treated with Metastron—clinically significant toxicity is rare.
- Metastron should be used with caution in patients with significantly compromised bone marrow from previous treatment. Caution should also be used in patients with platelet counts below 60,000 or white blood cell counts below 2,400.
- Some patients have reported a transient increase in bone pain lasting 36 to 72 hours following an injection—this can usually be controlled with analgesics.

AN IMPROVED QUALITY OF LIFE FOR PATIENTS.

- Metastron may improve patient quality of life, as measured by assessments of mood, mobility, appetite, sleep pattern, and analgesic consumption.[1-4]

Please see following page for full prescribing information.

METASTRON®
(STRONTIUM-89 CHLORIDE INJECTION)

An effective way to manage metastatic bone pain.

Please see us at the SNM Annual Meeting. Island #1021

METASTRON®
(STRONTIUM-89 CHLORIDE INJECTION)

An effective way to manage metastatic bone pain.

Consult your radiation safety officer for product availability or call Amersham Healthcare/ Medi-Physics Technical Services at 1-800-554-0157.

Metastron® (Strontium-89 Chloride Injection)

Description: Metastron is a sterile, non-pyrogenic, aqueous solution of Strontium-89 Chloride for intravenous administration. The solution contains no preservative.

Each milliliter contains:		
	Strontium Chloride	10.9 - 22.6 mg
	Water for Injection	q.s. to 1 mL

The radioactive concentration is 37 MBq/mL, 1 mCi/mL and the specific activity is 2.96 - 6.17 MBq/mg, 80-167 μCi/mg at calibration. The pH of the solution is 4 - 7.5.

Physical Characteristics: Strontium-89 decays by beta emission with a physical half-life of 50.5 days. The maximum beta energy is 1.463 MeV (100%). The maximum range of β- from Strontium-89 in tissue is approximately 8 mm.

Radioactive decay factors to be applied to the stated value for radioactive concentration at calibration, when calculating injection volumes at the time of administration, are given in Table 1.

Table 1: Decay of Strontium-89

Day*	Factor	Day*	Factor	Day*	Factor	Day*	Factor
-24	1.39	-12	1.18	+6	0.92	+18	0.78
-22	1.35	-10	1.15	+8	0.90	+20	0.76
-20	1.32	-8	1.12	+10	0.87	+22	0.74
-18	1.28	-6	1.09	+12	0.85	+24	0.72
-16	1.25	-4	1.06	+14	0.83	+26	0.70
-14	1.21	-2	1.03	+16	0.80	+28	0.68
		0 = calibration	1.00				

*Days before (-) or after (+) the calibration date stated on the vial.

Clinical Pharmacology: Following intravenous injection, soluble strontium compounds behave like their calcium analogs, clearing rapidly from the blood and selectively localizing in bone mineral. Uptake of strontium by bone occurs preferentially in sites of active osteogenesis; thus primary bone tumors and areas of metastatic involvement (blastic lesions) can accumulate significantly greater concentrations of strontium than surrounding normal bone.

Strontium-89 Chloride is retained in metastatic bone lesions much longer than in normal bone, where turnover is about 14 days. In patients with extensive skeletal metastases, well over half of the injected dose is retained in the bones.

Excretion pathways are two-thirds urinary and one-third fecal in patients with bone metastases. Urinary excretion is higher in people without bone lesions. Urinary excretion is greatest in the first two days following injection.

Strontium-89 is a pure beta emitter and Strontium-89 Chloride selectively irradiates sites of primary and metastatic bone involvement with minimal irradiation of soft tissues distant from the bone lesions. (The maximum range in tissue is 8 mm; maximum energy is 1.463 MeV.) Mean absorbed radiation doses are listed under the **Radiation Dosimetry** section.

Clinical trials have examined relief of pain in cancer patients who have received therapy for bone metastases (external radiation to indexed sites) but in whom persistent pain recurred. In a multi-center Canadian placebo-controlled trial of 126 patients, pain relief occurred in more patients treated with a single injection of Metastron than in patients treated with an injection of placebo. Results are given in the following tables.

Table 2 compares the percentage and number of patients treated with Metastron or placebo who had reduced pain and no increase in analgesic or radiotherapy re-treatment.

Table 2: Comparison of the effects of Strontium-89 and placebo, as adjunct to radiotherapy, on treatment outcome over time.

	Months Post-Treatment					
	1	2	3	4	5	6
Metastron	71.4% (n=42)	78.9% (n=38)	60.6% (n=33)	59.3% (n=27)	36.4% (n=22)	63.6% (n=22)
Placebo	61.4% (n=44)	57.1% (n=35)	55.9% (n=34)	25.0% (n=24)	31.8% (n=22)	35.0% (n=20)

At each visit, treatment success, defined as a reduction in a patient's pain score without any increase in analgesic intake and without any supplementary radiotherapy at the index site, was more frequent among patients assigned to Metastron than to placebo.

Table 3 compares the number and percentage of patients treated with Metastron or placebo as an adjunct to radiotherapy who were pain free without analgesic at the intervals shown.

Table 3: Comparison of the effects of Strontium-89 and placebo, as adjunct to radiotherapy, on reduction of pain score and analgesic score to zero.

	Months Post-Treatment						
	1	2	3	4	5	6	9
Metastron	6 14.3% (n=42)	5 13.2% (n=38)	5 15.2% (n=33)	3 11.1% (n=27)	4 18.2% (n=22)	4 18.2% (n=22)	2 18.2% (n=11)
Placebo	3 6.8% (n=44)	3 8.6% (n=35)	2 5.9% (n=34)	0 (n=24)	1 4.5% (n=22)	1 5% (n=20)	0 (n=17)

The number of patients classified at each visit as treatment successes who were pain free at the index site *and* required no analgesics was consistently higher in the Metastron group.

New pain sites were less frequent in patients treated with Metastron.

In another clinical trial, pain relief was greater in a group of patients treated with Metastron compared with a group treated with non-radioactive strontium-88.

Indications and Usage: Metastron (Strontium-89 Chloride Injection) is indicated for the relief of bone pain in patients with painful skeletal metastases.

The presence of bone metastases should be confirmed prior to therapy.

Contraindications: None known.

Warnings: Use of Metastron in patients with evidence of seriously compromised bone marrow from previous therapy or disease infiltration is not recommended unless the potential benefit of the treatment outweighs its risks. Bone marrow toxicity is to be expected following the administration of Metastron, particularly white blood cells and platelets. The extent of toxicity is variable. It is recommended that the patient's peripheral blood cell counts be monitored at least once every other week. Typically, platelets will be depressed by about 30% compared to pre-administration levels. The nadir of platelet depression in most patients is found between 12 and 16 weeks following administration of Metastron. White blood cells are usually depressed to a varying extent compared to pre-administration levels. Thereafter, recovery occurs slowly, typically reaching pre-administration levels six months after treatment unless the patient's disease or additional therapy intervenes.

In considering repeat administration of Metastron, the patient's hematologic response to the initial dose, current platelet level and other evidence of marrow depletion should be carefully evaluated.

Verification of dose and patient identification is necessary prior to administration because Metastron delivers a relatively high dose of radioactivity.

Metastron may cause fetal harm when administered to a pregnant woman. There are no adequate and well-controlled studies in pregnant women. If this drug is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant.

Precautions: Metastron is not indicated for use in patients with cancer not involving bone. Metastron should be used with caution in patients with platelet counts below 60,000 and white cell counts below 2,400.

Radiopharmaceuticals should only be used by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Metastron, like other radioactive drugs, must be handled with care and appropriate safety measures taken to minimize radiation to clinical personnel.

In view of the delayed onset of pain relief, typically 7 to 20 days post injection, administration of Metastron to patients with very short life expectancy is not recommended.

A calcium-like flushing sensation has been observed in patients following a rapid (less than 30-second injection) administration.

Special precautions, such as urinary catheterization, should be taken following administration to patients who are incontinent to minimize the risk of radioactive contamination of clothing, bed linen and the patient's environment.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Data from a repetitive dose animal study suggests that Strontium-89 Chloride is a potential carcinogen. Thirty-three of 40 rats injected with Strontium-89 Chloride in ten consecutive monthly doses of either 250 or 350 μCi/kg developed malignant bone tumors after a latency period of approximately 9 months. No neoplasia was observed in the control animals. Treatment with Strontium-89 Chloride should be restricted to patients with well documented metastatic bone disease.

Adequate studies with Strontium-89 Chloride have not been performed to evaluate mutagenic potential or effects on fertility.

Pregnancy: Teratogenic effects.

Pregnancy Category D. See **Warnings** section.

Nursing Mothers: Because Strontium acts as a calcium analog, secretion of Strontium-89 Chloride into human milk is likely. It is recommended that nursing be discontinued by mothers about to receive intravenous Strontium-89 Chloride. It is not known whether this drug is excreted in human milk.

Pediatric Use: Safety and effectiveness in children below the age of 18 years have not been established.

Adverse Reactions: A single case of fatal septicemia following leukopenia was reported during clinical trials. Most severe reactions of marrow toxicity can be managed by conventional means.

A small number of patients have reported a transient increase in bone pain at 36 to 72 hours after injection. This is usually mild and self-limiting, and controllable with analgesics. A single patient reported chills and fever 12 hours after injection without long-term sequelae.

Dosage and Administration: The recommended dose of Metastron is 148 MBq, 4 mCi, administered by slow intravenous injection (1-2 minutes). Alternatively, a dose of 1.5 - 2.2 MBq/kg, 40-60 μCi/kg body weight may be used.

Repeated administrations of Metastron should be based on an individual patient's response to therapy, current symptoms, and hematologic status, and are generally not recommended at intervals of less than 90 days.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Radiation Dosimetry: The estimated radiation dose that would be delivered over time by the intravenous injection of 37 MBq, 1 mCi of Strontium-89 to a normal healthy adult is given in Table 4. Data are taken from the ICRP publication "Radiation Dose to Patients from Radiopharmaceuticals"-ICRP #53, Vol. 18 No. 1-4, Page 171, Pergamon Press, 1988.

Table 4: Strontium-89 Dosimetry

Organ	mGy/MBq	rad/mCi	Organ	mGy/MBq	rad/mCi
Bone Surface	17.0	63.0	Testes	0.8	2.9
Red Bone Marrow	11.0	40.7	Ovaries	0.8	2.9
Lower Bowel Wall	4.7	17.4	Uterine Wall	0.8	2.9
Bladder Wall	1.3	4.8	Kidneys	0.8	2.9

When blastic osseous metastases are present, significantly enhanced localization of the radiopharmaceutical will occur with correspondingly higher doses to the metastases compared with normal bones and other organs.

The radiation dose hazard in handling Strontium-89 Chloride injection during dose dispensing and administration is similar to that from phosphorus-32. The beta emission has a range in water of about 8 mm (max.) and in glass of about 3 mm, but the bremsstrahlung radiation may augment the contact dose.

Measured values of the dose on the surface of the unshielded vial are about 65 mR/minute/mCi.

It is recommended that the vial be kept inside its transportation shield whenever possible.

How Supplied: Metastron is supplied in a 10 mL vial containing 148 MBq, 4 mCi. The vial is shipped in a transportation shield with approximately 3 mm lead wall thickness, package insert, and two therapeutic agent warning labels.

The vial and its contents should be stored inside its transportation container at room temperature (15-25° C, 59-77° F).

The calibration date (for radioactivity content) and expiration date are quoted on the vial label. The expiration date will be 28 days after calibration. Stability studies have shown no change in any of the product characteristics monitored during routine product quality control over the period from manufacture to expiration.

This radiopharmaceutical is licensed by the Illinois Department of Nuclear Safety for distribution to persons licensed pursuant to 32 Illinois Adm. Code 330.260 (a) and Part 335 Subpart F.335.5010 or under equivalent licenses of the USNRC or an Agreement State.

THIS PRODUCT INFORMATION ISSUED JUNE, 1993. Product Code: SMS.2PA

Manufactured by: **Amersham International plc** Amersham, England

Medi-Physics, Inc. 2636 S. Clearbrook Drive Arlington Heights, Illinois 60005

References:

1. Data on file, Amersham International plc, Amersham, England. 2. Lewington VJ, McEwan AJ, Ackery DM, et al. A prospective, randomised double-blind crossover study to examine the efficacy of strontium-89 in pain palliation in patients with advanced prostate cancer metastatic to bone. *Eur J Cancer*. 1991;27:954-958. 3. Porter AT, McEwan AJB, Powe JE, et al. Results of a randomized phase-III trial to evaluate the efficacy of strontium-89 adjuvant to local field external beam irradiation in the management of endocrine resistant metastatic prostate cancer. *Int J Radiat Oncol Biol Phys*. 1993;25:805-813. 4. Blake GM, Zivanovic MA, McEwan AJ, et al. "Sr radionuclide therapy: dosimetry and haematological toxicity in two patients with metastasising prostatic carcinoma. *Eur J Nucl Med*. 1987;13:41-46. 5. Blake GM, Zivanovic MA, McEwan AJ, et al. Sr-89 therapy: strontium kinetics in disseminated carcinoma of the prostate. *Eur J Nucl Med*. 1986;12:447-454.

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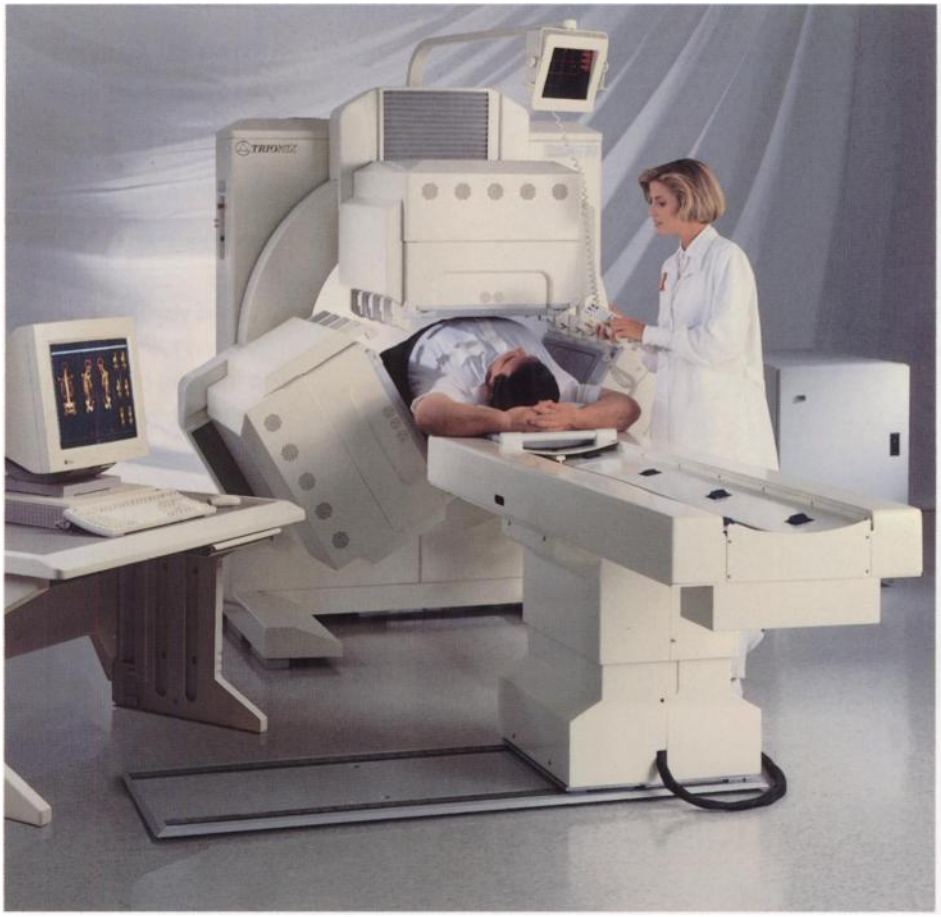

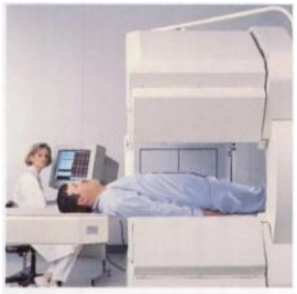

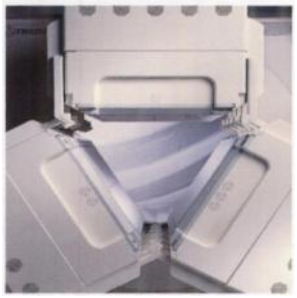

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TRIONIX Technical Notes: Vol.2, No.1

Chun Bin Lim, Ph.D

TRIONIX

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Hospital of St. Raphael, New Haven, Connecticut	Dr. Caride	July 1994
ASAN Medical Center, Seoul, Korea	Dr. Moon, Dr. Lee	July 1994
Mt. Godinne, UCL, Brussels, Belgium	Dr. DeCoster	September 1994
Centennial, Nashville, Tennessee	Dr. Bell	November 1994
VA Indianapolis & University of Indiana	Dr. Witt, Dr. Burt	January 1995

TRIAD XLT 9", Cardiac/Brain SPECT

Validation Sites	Validators	Installed Month
Johns Hopkins, Baltimore, Maryland (two systems)	Dr. Natarajan	February, June 1993
VA San Francisco, UC, San Francisco, California	Dr. Gerard	February 1993
Duke, Durham, North Carolina (two systems)	Dr. Coleman, Dr. Jaszczak	June 1993, August 1994
University of Virginia, Charlottesville, Virginia	Dr. Teats, Dr. Croft	June 1993
Memorial Mission, Asheville, North Carolina	Dr. Peterson	July 1993
Austin, Heidelberg, Australia	Dr. Mackay	September 1993
Pontiac Osteopathic, Pontiac, Michigan	Dr. Kotlyarov	October 1993
Royal Prince Alfred, Sidney, Australia	Dr. Van der Wal	November 1993
KUL, Leuven, Belgium	Dr. DeRoo, Dr. Mortelmans	December 1993
Karolinska, Stockholm, Sweden	Dr. Larsson	February 1994
Samsung Medical Center, Seoul, Korea	Dr. Kim	March 1994
Cleveland Clinic Foundation, Cleveland, Ohio	Dr. Go, Dr. McIntyre	October 1994

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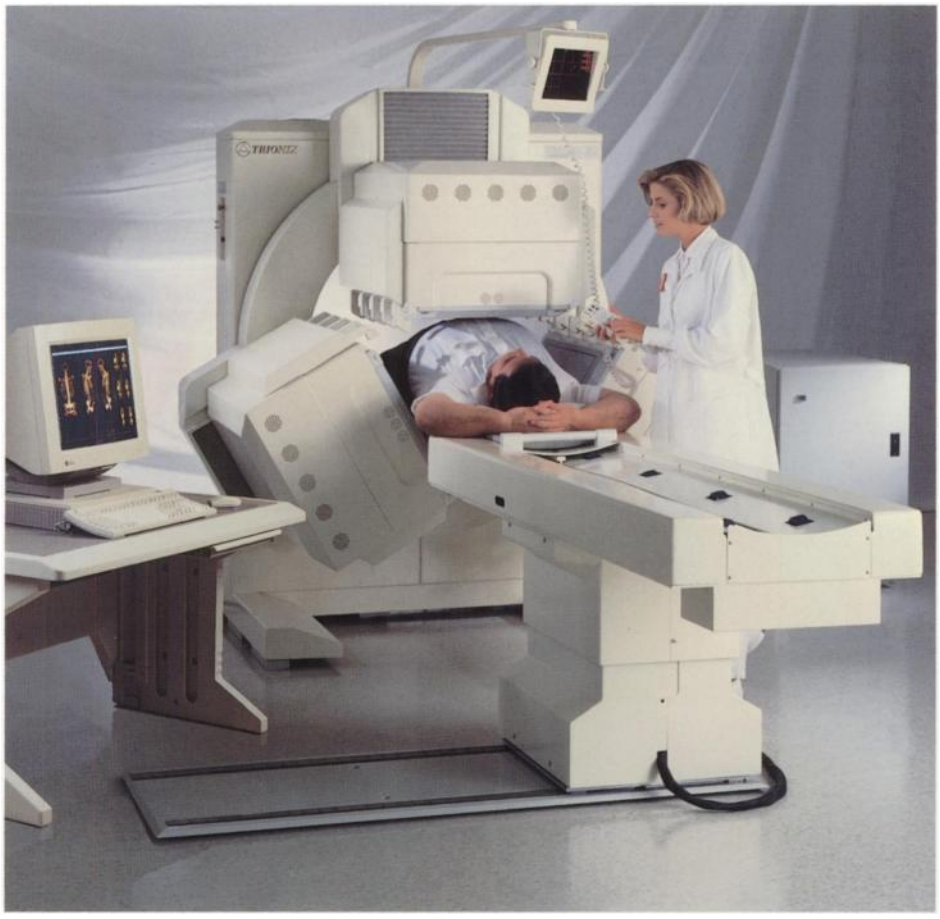

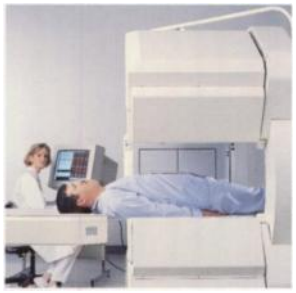

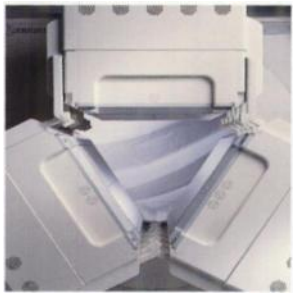

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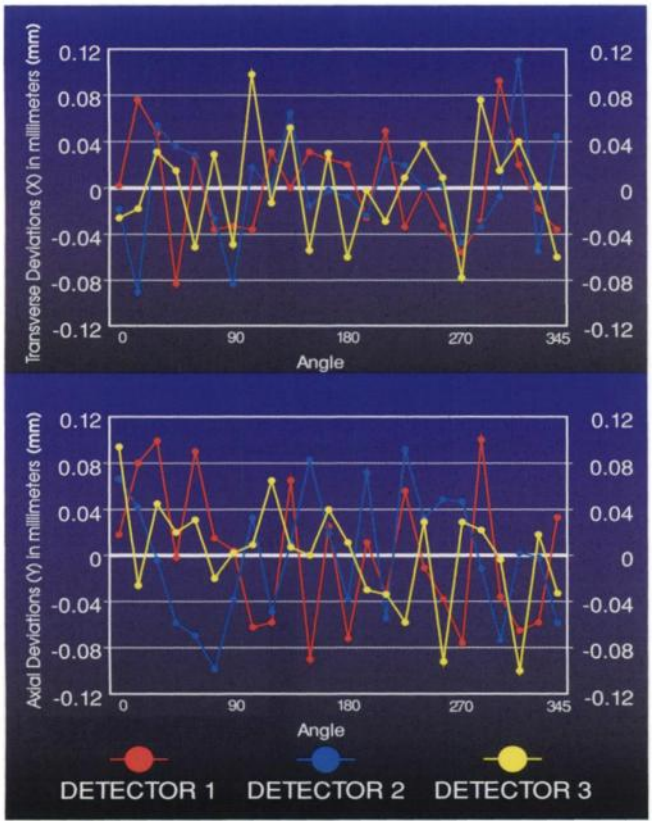

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Trionix engineers designed and validated "The Next Generation" TRIAD XLT 20 Whole BodySPECT imaging system to provide images of unsurpassed diagnostic detail. Superior image resolution is the result of precision system integration, both structural and system design. The solid steel single ring gantry, precision gearing, and radial motion-only detector travel, in combination with alignment digital distortion corrections (ELFS) guarantees consistent "Center of Rotation" and axial detector alignment accuracy to 0.1 mm precision.

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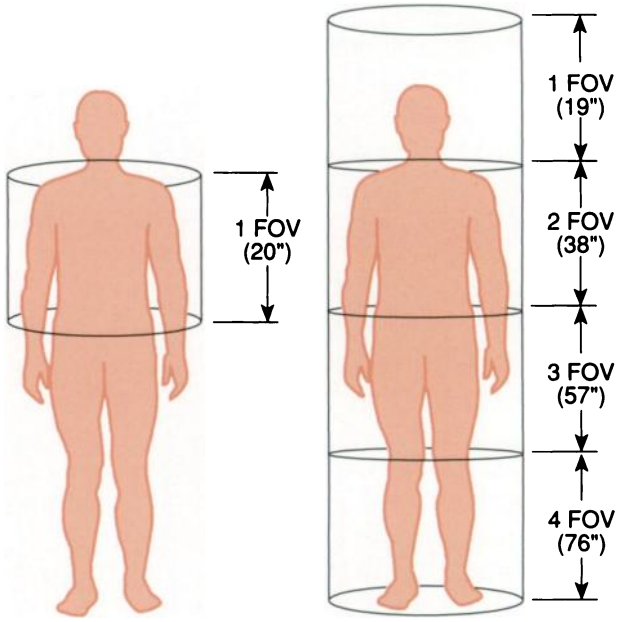

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511 keV F-18 FDG SPECT

TI SPECT

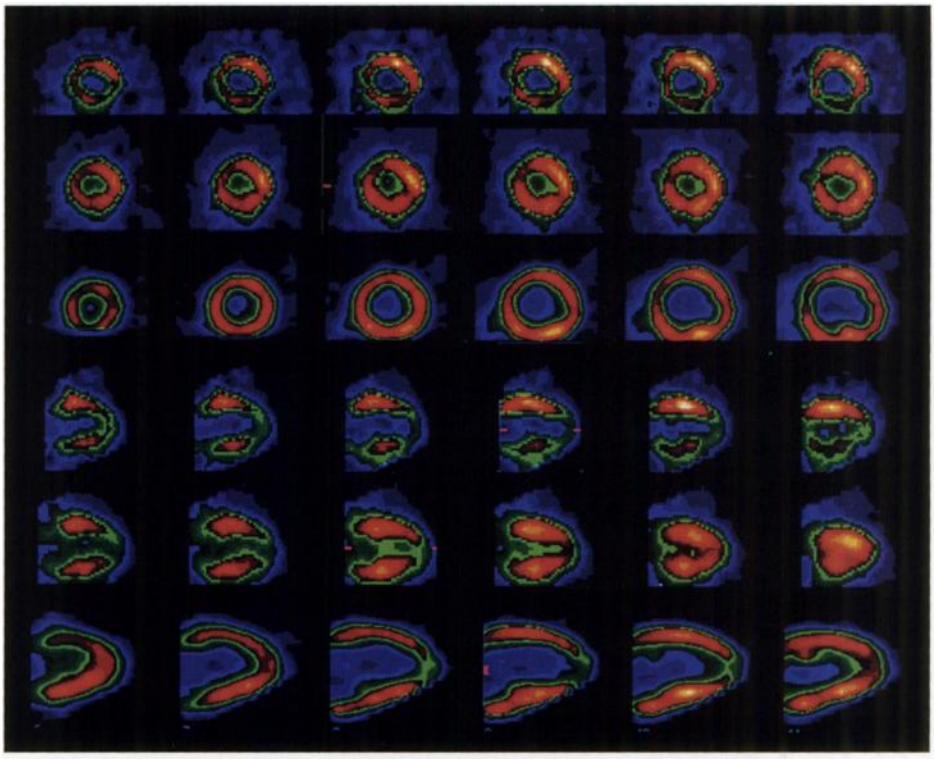
FDG-SPECT

FDG-PET

TI-SPECT

FDG-SPECT

FDG-PET



Feb. 1995 JNM Cover Images of heart muscle uptake scanned by TRIAD 88 with HE Collimators.
Courtesy of Dr. R. Burt et. al. VA Medical Center and Indiana University School of Medicine and JNM.

1995 SNM Abstract

SPECT Imaging by 511 keV Photons V. Rappoport, E. Q. Chen, J. Jiang, B. Kline, C. B. Lim.
TRIONIX Research Laboratory, Inc., Twinsburg, OH and Cleveland Clinic, Cleveland, OH

F-18 labeled FDG is found very useful to provide information for brain, heart and whole body studies with PET systems. We have investigated SPECT system characteristics in response to 511 keV photons on TRIAD XLT detectors with specially designed high energy collimators. Intrinsic characteristics were measured: energy resolution is $\Delta E/E = 8.96\%$; spatial resolution is FWHM 1.92 mm and 1.87 mm in UFOV and CFOV respectively. To test intrinsic planar image quality the resolution bar phantom with smallest bars of 2.12 mm width was used. The system performance was measured. The following SPECT studies were performed: four hot spheres with diameters in the range of 1.27 to 2.54 cm in 20 cm diameter cylinder filled with water; cardiac phantom in water-filled cylinder with background activity of (10:1). Cold lesion defects of dimensions 15 mm x 10 mm and 20 mm x 10 mm were inserted in the phantom. After reconstruction all spheres and both defects in cardiac phantom were clearly visible.

The reconstructed spatial resolution was measured using a Na-22 line source of 1 mm diameter. The line source was placed in the center of 20 cm diameter cylinder filled with water, and a SPECT study was performed with 11 cm distance between source and collimator surface. After reconstruction the line spread function was measured. The FWHM and FWTM were 10.2 mm and 22.7 mm respectively.

Brain and cardiac studies of the same patients were performed both on SPECT and PET systems. Comparative analysis supports the possibility of performing clinical SPECT studies with 511 keV agents. In conclusion, despite the lower sensitivity and somewhat poorer resolution, FDG SPECT studies may provide diagnostic information comparable to PET at a significantly less system cost.

Chun Bin Lim, Ph.D

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February, 1995

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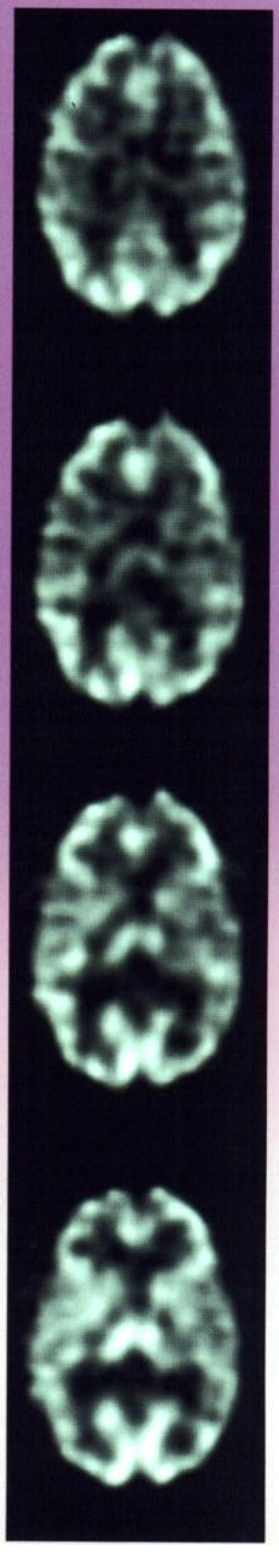

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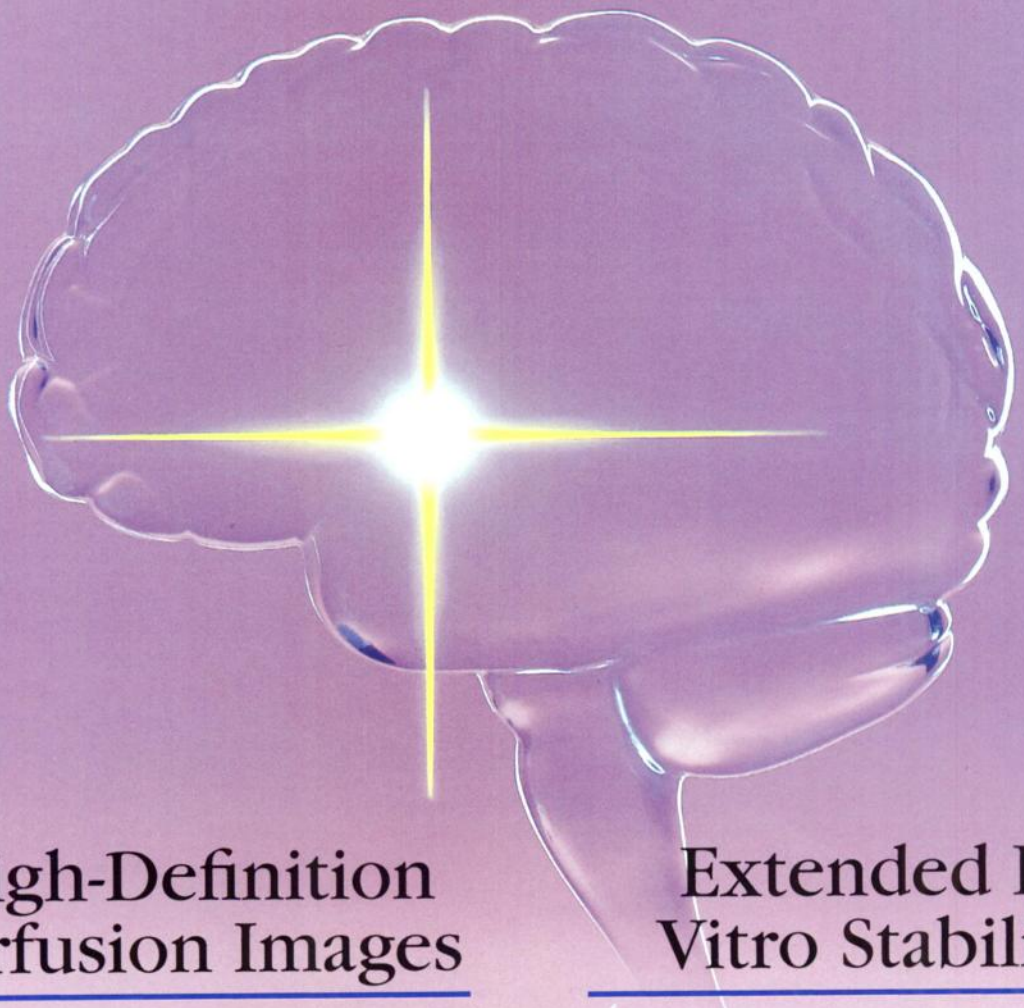

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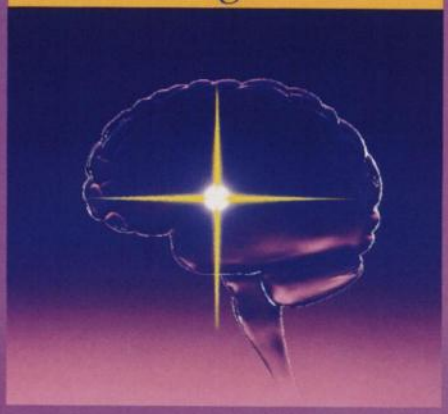

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INDICATIONS
Neurolite single photon emission computerized tomography (SPECT) is indicated as an adjunct to conventional CT or MRI imaging in the localization of stroke in patients in whom stroke has already been diagnosed.

Neurolite is not indicated for assessment of functional viability of brain tissue. Also, Neurolite is not indicated for distinguishing between stroke and other brain lesions.

CONTRAINDICATIONS
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WARNINGS
None known.

PRECAUTIONS
General
USE WITH CAUTION IN PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT. TECHNETIUM Tc99m BICISATE IS ELIMINATED PRIMARILY BY RENAL EXCRETION. WHETHER TECHNETIUM Tc99m BICISATE IS DIALYZABLE IS NOT KNOWN. DOSE ADJUSTMENTS IN PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT HAVE NOT BEEN STUDIED.

Patients should be encouraged to drink fluids and to void frequently during the 2-6 hours immediately after injection to minimize radiation dose to the bladder and other target organs.

Contents of the vials are intended only for use in the preparation of Technetium Tc99m Bicisate and are not to be administered directly to the patient without first undergoing the preparation procedure.

The contents of each vial are sterile and nonpyrogenic. To maintain sterility, aseptic technique must be used during all operations in the manipulation and administration of Neurolite.

Technetium Tc99m Bicisate should be used within six hours of the time of preparation.

As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other people.

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. When tested in vitro, Neurolite prepared with decayed generator eluate induced unscheduled DNA synthesis in rat hepatocytes and caused an increased frequency of sister chromatid exchanges in CHO cells; but, it did not induce chromosome aberrations in human lymphocytes or cause gene mutations in the Ames test or in a CHO/HGPRT test. Unreacted bicisate dihydrochloride increased the apparent rate of gene mutation of the TA 97a strain of *S. typhimurium* in the Ames test; but, it did not demonstrate clastogenic activity in an in vivo micronucleus assay in mice.

Pregnancy: Teratogenic Effects
Pregnancy Category C
Animal reproduction studies have not been conducted with Technetium Tc99m Bicisate. It is also not known whether Technetium Tc99m Bicisate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, Technetium Tc99m Bicisate should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

Nursing Mothers
Technetium Tc99m Pertechnetate can be excreted in human milk. Therefore, formula should be substituted for breast milk until the technetium has cleared from the body of the nursing woman.

Pediatric Use
Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
In clinical trials, Neurolite has been administered to 1022 subjects (262 normals, 760 patients). Of these, 548 (54%) were men and 473 (46%) were women. The mean age was 58 years (range 17 to 92 years). In the 760 patients who had experienced neurologic events, there were 11 (1.4%) deaths, none of which were clearly attributed to Neurolite.

A total of 60 subjects experienced adverse reactions; the adverse reaction rates were comparable in the <65 year and the >65 year age groups.

The following adverse effects were observed in ≤1% of the subjects: headache, dizziness, seizure, agitation/anxiety, malaise/somnolence, parosmia, hallucinations, rash, nausea, syncope, cardiac failure, hypertension, angina, and apnea/cyanosis.

In clinical trials of 197 patients, there were inconsistent changes in the serum calcium and phosphate levels. The cause of the changes has not been identified and their frequency and magnitude have not been clearly characterized. None of the changes required medical intervention.

DOSAGE AND ADMINISTRATION
Before administration, a patient should be well hydrated. After administration, the patient should be encouraged to drink fluids liberally and to void frequently.

The recommended dose range for intravenous administration for a 70 kg patient is 370 - 1110 MBq (10-30 mCi). Dose adjustments for age, weight, gender, or renal or hepatic impairment have not been studied.

The dose for the patient should be measured by a suitable radioactivity calibration system immediately before administration to the patient. Radiochemical purity should be checked before administration to the patient.

Neurolite, like other parenteral drug products, should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Preparations containing particulate matter or discoloration should not be administered. They should be disposed of in a safe manner, in compliance with all applicable regulations.

Prior to reconstitution, vial A and vial B are stored at 15°-25°C. Protect vial A from light.

Store at room temperature (15°-30°C) after preparation.

Aseptic techniques and effective shielding should be employed in withdrawing doses for administration to patients. Waterproof gloves and effective shielding should be worn when handling the product.

RADIATION DOSIMETRY
The radiation doses to organs and tissues of an average patient (70 kg) for Technetium Tc99m Bicisate injected intravenously for 370 MBq (10 mCi) are shown in Table 4 and for 1110 MBq (30 mCi) are shown in Table 5.

Table 4.—Radiation Absorbed Doses From 370 MBq (10 mCi) of Technetium Tc99m Bicisate

	Estimated Absorbed Radiation Dose[2]			
	2.0 Hr. Void		4.8 Hr. Void	
	mGy/ 370 MBq	rads/ 10 mCi	mGy/ 370 MBq	rads/ 10 mCi
Organ				
Bone Surfaces	1.26	0.13	1.41	0.14
Brain	2.04	0.20	2.04	0.20
Gallbladder Wall	9.25	0.91	9.25	0.92
Intestine Wall (Lower Large)	4.81	0.47	5.55	0.55
Intestine (Small)	3.48	0.35	3.70	0.38
Intestine Wall (Upper Large)	5.92	0.61	6.29	0.63
Kidneys	2.70	0.27	2.74	0.27
Liver	1.96	0.20	2.00	0.20
Lungs	0.74	0.08	0.74	0.08
Ovaries	2.00	0.22	2.96	0.30
Red Marrow	0.89	0.09	1.00	0.10
Testes	0.81	0.08	1.33	0.13
Thyroid	1.30	0.13	1.30	0.13
Urinary Bladder Wall	11.10	1.10	27.01	2.70
Total Body	0.89	0.09	1.07	0.11

Table 5.—Radiation Absorbed Doses From 1110 MBq (30 mCi) of Technetium Tc99m Bicisate

	Estimated Absorbed Radiation Dose[2]			
	2.0 Hr. Void		4.8 Hr. Void	
	mGy/ 1110 MBq	rads/ 30 mCi	mGy/ 1110 MBq	rads/ 30 mCi
Organ				
Bone Surfaces	3.77	0.39	4.22	0.42
Brain	6.11	0.61	6.11	0.61
Gallbladder Wall	27.75	2.73	27.75	2.76
Intestine Wall (Lower Large)	14.43	1.41	16.65	1.65
Intestine (Small)	10.43	1.05	11.10	1.14
Intestine Wall (Upper Large)	17.76	1.83	18.87	1.89
Kidneys	8.10	0.81	8.21	0.81
Liver	5.88	0.60	5.99	0.60
Lungs	2.22	0.23	2.22	0.23
Ovaries	5.99	0.66	8.88	0.90
Red Marrow	2.66	0.26	3.00	0.29
Testes	2.44	0.24	4.00	0.39
Thyroid	3.89	0.39	3.89	0.39
Urinary Bladder Wall	33.33	3.33	81.03	8.10
Total Body	2.66	0.27	3.22	0.33

[2]Dosimetry calculated using the MIRD software program at Oak Ridge Associated Universities, P.O. Box 117, Oakridge, TN, 29 July 1988.

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References: 1. Holman BL, Hellman RS, Goldsmith SJ, et al. Biodistribution, dosimetry, and clinical evaluation of technetium-99m ethyl cysteinate dimer in normal subjects and in patients with chronic cerebral infarction. *J Nucl Med.* 1989;30:1018-1024.
2. Vallabhajosula S, Zimmerman RE, Picard M, et al. Technetium-99m ECD: a new brain imaging agent: in vivo kinetics and biodistribution studies in normal human subjects. *J Nucl Med.* 1989;30:599-604.

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* References:

1) Shapiro B., Copp J.E., Sisson J.C., Eyre P.L., Wallis J., Beirwaltes W.H.: Iodine-131 Meta-iodobenzylguanidine for Locating of Suspected Pheochromocytoma: Experience in 400 Cases; J. Nucl Med, 1985, 26: 576-585.

2) Pochedly, C; ed., Neuroblastoma: Tumor Biology and Therapy, CRC Press, Boca Raton, FL, 1990; ch. 8; p. 182

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BRIEF SUMMARY
Iobenguane Sulfate I 131 Injection. Diagnostic-For Intravenous Use

DESCRIPTION
Iobenguane Sulfate I 131 Injection is a sterile, pyrogen free radiopharmaceutical for intravenous injection. Each milliliter contains 0.69 mg of iobenguane sulfate, 85.1 MBq (2.30 mCi) of I 131 (as iobenguane sulfate I 131 at calibration), 0.36 mg of sodium acetate, 0.27 mg of acetic acid, 4.2 mg of sodium chloride, 0.56 mg of methyl paraben, 0.56 mg of propylparaben and 0.01 mL of benzyl alcohol. Iobenguane Sulfate I 131 is also known as I 131-meta-iodobenzylguanidine sulfate (I 131 mIBG).

INDICATIONS AND USAGE
Iobenguane Sulfate I 131 Injection is indicated as an adjunctive diagnostic agent in the localization of primary or metastatic pheochromocytomas and neuroblastomas.

CONTRAINDICATIONS
Iobenguane Sulfate I 131 is contraindicated in patients with known hypersensitivity to iobenguane sulfate.

WARNINGS
As with other I 131 containing agents, in order to decrease thyroid accumulation of I 131, block the thyroid gland with iodine. (See Dosage and Administration section)

During and following the injection, patients with known or suspected pheochromocytoma should be carefully monitored for hypertensive crises.

PRECAUTIONS
General
IOBENGUANE SULFATE I 131 IS CLEARED BY GLOMERULAR FILTRATION AND IS NOT DIALYZABLE. Caution should be exercised when administering the drug to renally impaired patients. Iobenguane Sulfate I 131 is not recommended in anephric patients. The radiation dose to the anephric patient would be substantially increased due to the delayed biological elimination of the drug. Also, because of the lack of clearance, the target-to-back ground ratios would severely compromise the outcome of the study. Iobenguane Sulfate I 131 use in patients with impaired renal function should be carefully considered. As with all radio-iodinated compounds, the patient should be well hydrated before and during examination.

Although iodinated contrast imaging agents have been confirmed to cause anaphylactic reactions in patients with hypersensitivity to iodine, the incidence of hypersensitivity reactions to Iobenguane Sulfate I 131 is rare. Since hypersensitivity or immune reactions are not concentration dependent, emergency treatment measures should be available.

Cardiac:
Electrocardiographic (ECG) changes have been documented in dogs after the administration of 18 times the mg/m^2 conversion of the maximum human dose of Iobenguane Sulfate I 131. The maximum no observable effect level (NOEL) is not known. It is unknown if Iobenguane Sulfate I 131 can produce changes in ECG recordings in man.

Drug Interactions:
There are literature reports about patients and about in-vitro systems which suggest that the following drugs have the potential to decrease uptake of Iobenguane Sulfate I 131 in neuroendocrine tumors and may lead to false negative results if administered concomitantly: anti-hypertensives (labetalol, reserpine, calcium channel blockers), amitriptyline and derivatives, imipramine and derivatives, doxepin, amoxapin, and loxapin, sympathetic-amines (phenylephrine, phenylpropalamine, pseudoephedrine, ephedrine) and cocaine. The clinical studies were not designed to show which drugs could cause false negative results. It is unknown if other drugs in the same classes have the same potential to inhibit the uptake of Iobenguane Sulfate I131. Increasing the dose of Iobenguane Sulfate I 131 dose will not overcome any potential uptake-limiting effect of these drugs.

Normal biodistribution and excretion of Iobenguane Sulfate I 131 leads to localization in adrenergic storage granules of the adrenal gland. It is also localized in salivary glands, liver, spleen and urinary bladder. As in all nuclear imaging procedures, careful positioning may be useful in distinguishing normal biodistribution of the agent from localization in sites of pathology.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies with Iobenguane Sulfate I 131 have not been conducted to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy (Category C):
Animal reproduction studies have not been conducted with Iobenguane Sulfate I 131. It is also not known whether Iobenguane Sulfate I 131 can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity. Therefore, Iobenguane Sulfate I 131 should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:
I 131 is excreted in human milk; it is not known if Iobenguane Sulfate I 131 is excreted in human milk. Therefore, breast feeding should be substituted with formula feeding until the Iobenguane Sulfate I 131 has cleared from the body of the nursing woman.

Pediatric Use
The safety and effectiveness of Iobenguane Sulfate I 131 have been reasonably established in children with neuroblastoma and pheochromocytoma.

Safety, effectiveness, metabolism, urinary excretion and tumor specificity of Iobenguane Sulfate I 131 is unknown in neonates.

ADVERSE REACTIONS
Transient episodes of marked hypertension have been reported in patients after injection of Iobenguane Sulfate I 131. Some of these patients were on anti-hypertensives and others were not.

Nausea, vomiting and sleepiness have been reported after injection of higher than the recommended doses of Iobenguane Sulfate I 131. The no effect level for these reactions has not been identified. An episode of fever, chills and hypotension has been reported. In clinical trials, no deaths have been attributed to the drug.

DOSAGE AND ADMINISTRATION
Before administration of Iobenguane Sulfate I 131, the patient's thyroid gland should be blocked with Potassium Iodide Oral Solution (120 mg KI/day = 0.12 mL/day) or Lugol's Solution (up to 40 mg I/day = 0.3 mL/day). The blocking iodine should be administered one day before and daily for 5 to 7 days after the dose of Iobenguane Sulfate I 131.

Adults:
The recommended dose in adults is 0.5 mCi. In obese patients over 1.7 m^2 (65 kg), the dose should be 0.3 mCi/m^2 up to a maximum of 1.0 mCi.

Children:
The recommended dose in children is 0.3 mCi/m^2 up to a maximum total dose of 0.5 mCi. The minimum recommended dose for adequate imaging is 0.135 mCi.

Iobenguane Sulfate I 131 should be injected by slow intravenous infusion over 15-30 seconds (longer if necessary). Since the possibility of rebound hypertension exists, the patient's vital signs should be carefully monitored during and after injection.

In order to maintain sterility, it is essential that the user follow directions and adhere to strict aseptic procedure. As in the use of any radioactive material, care should be taken to insure minimum radiation exposure to the patient and clinical personnel.

Waterproof gloves should be worn by the user and a shielded syringe should be used during the preparation and administration of the dose. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use of radio-nuclides, and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

RADIATION DOSIMETRY
The estimated absorbed radiation doses to adults and children from an intravenous dose of Iobenguane Sulfate I 131 are shown in Table 4.*

Table 4: Estimated Absorbed Radiation Doses*: Iobenguane Sulfate I-131

Organ	Adult		15 Years		10 Years		5 Years		1 Year	
	mGy/ 37MBq	rads/ mCi	mGy/ 18.5MBq	rads/ 0.5mCi	mGy/ 18.5MBq	rads/ 0.5mCi	mGy/ 18.5MBq	rads/ 0.5mCi	mGy/ 18.5MBq	rads/ 0.5mCi
Urinary Bladder Wall	29.6	2.96	18.5	1.85	27.8	2.78	42.6	4.26	83.3	8.33
Liver	29.2	2.92	18.5	1.85	29.6	2.96	42.6	4.26	83.3	8.33
Spleen	21.8	2.18	15.7	1.57	24.1	2.41	38.9	3.89	72.2	7.22
Heart Wall	14.1	1.41	9.1	0.91	14.1	1.41	22.2	2.22	40.7	4.07
Adrenal Medulla	7.8	0.78	5.4	0.54	8.0	0.80	10.7	1.07	16.5	1.65
Gallbladder Wall	5.2	0.52	3.0	0,30	4.3	0.43	6.7	0.67	12.6	1.26
Pancreas	4.1	0.41	2.4	0.24	3.9	0.39	5.9	0.59	10.9	1.09
Thyroid	3.4	0.34	2.6	0.26	4.1	0.41	8.7	0.87	16.5	1.65
Kidneys	3.3	0.33	2.0	0.20	3.1	0.31	4.8	0.48	8.7	0.87
Uterus	3.3	0.33	2.0	0.20	3.3	0.33	5,2	0.52	9.4	0.94
Ovaries	2.7	0.27	1.7	0.17	2.8	0.28	4.3	0.43	8.1	0.81
Total Body	2.3	0.23	1.4	0.14	2.3	0.23	3.3	0.33	6.4	0.64
Testes	2.2	0.22	1.4	0.14	2.2	0.22	3.7	0.37	7.0	0.70
Brain	1.8	0.18	1.1	0.11	1.9	0.19	3.1	0.31	5.9	0.59

*ORISE, Radiation Internal Dose Information Center, Radiation Dose Estimates for I-131 mIBG Intravenous Administration.

The following organs each receive less than 1 rad per procedure: breasts, LLI wall, small intestine, stomach, ULI wall, lungs, muscle, red marrow, bone surfaces, skin and thymus.

If 0.5 mCi of Iobenguane Sulfate I 131 is used, the organ burden would be half of the doses listed above. The thyroid gland estimated burden is in the unblocked state. When the thyroid gland is blocked with Lugol's solution, uptake is minimal.

Peak scans were generally noted at 48 hours post-injection. However, serial scans at 24, 48 and 72 hours post-injection may be needed to optimally define the tumor.

HOW SUPPLIED:
Iobenguane Sulfate I 131 Injection is supplied in a 2 mL glass vial as a sterile, nonpyrogenic solution containing, at calibration time, 85.1 MBq/ml (2.3 mCi/ml) of Iobenguane Sulfate I 131 Injection. Store the drug at freezer temperature (-20 to -10°C).

NOTE:
Two to three hours prior to use, thaw the vial in the leaded container, at room temperature. Discard the unused portion of drug after 4-6 hours if kept at room temperature.

In conformance with USP recommendations, Iodine 131 preparations should not be used after the expiration date stated on the label.

NDC# 0455670100

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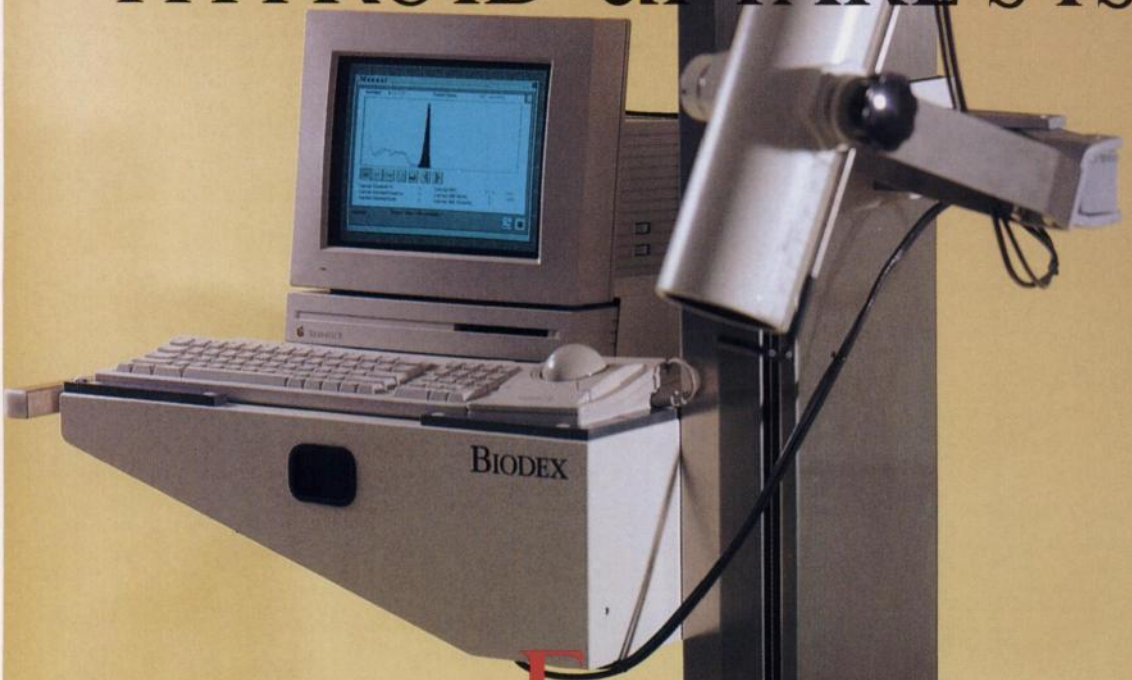

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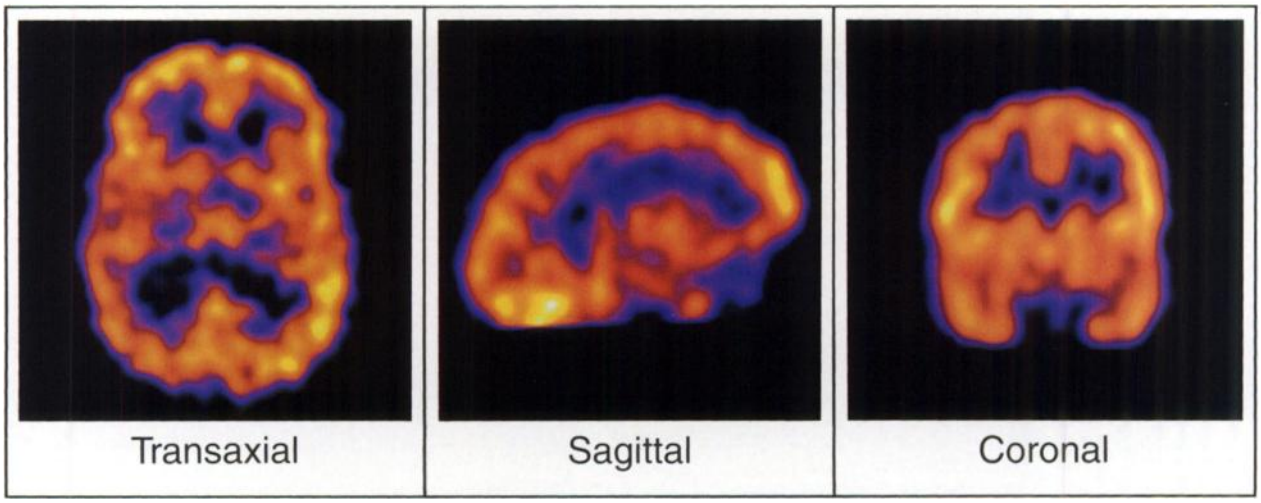

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DESCRIPTION

The Ceretec kit is supplied as five packs of three vials for use in the preparation of a technetium Tc99m exametazime intravenous injection as a diagnostic radiopharmaceutical for use as an adjunct in the detection of altered regional cerebral perfusion and for the radiolabeling of autologous leukocytes. Each vial of Ceretec contains a pre-dispensed sterile, non-pyrogenic lyophilized mixture of 0.5 mg exametazime [(RR,SS)-4,8-diaza-3,6,6,9-tetramet hylundecane-2,10-dione bisoxime], 7.6 µg stannous chloride dihydrate (minimum stannous tin 0.6 µg; maximum total stannous and stannic tin 4.0 µg per vial) and 4.5 mg sodium chloride, sealed under nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

In addition, each package contains five 1 mL vials of Methylene Blue Injection USP 1% containing 10 mg methylene blue USP in water for injection q.s., pH adjusted with sodium hydroxide and/or hydrochloric acid, when necessary. Methylene Blue Injection USP is a sterile, non-pyrogenic solution of phenothiazin-5-ium,3,7-bis (dimethylamino)-chloride, trihydrate. Each package also contains five 4.5 mL vials of 0.003 M Monobasic Sodium Phosphate USP and Dibasic Sodium Phosphate USP in 0.9% Sodium Chloride Injection USP. The solution is sterile and non-pyrogenic. Each mL contains 0.276 mg monobasic sodium phosphate monohydrate, 0.142 mg dibasic sodium phosphate anhydrous and 9 mg sodium chloride in water for injection q.s. The total calculated osmolarity of the 0.003 M Monobasic Sodium Phosphate USP and Dibasic Sodium Phosphate USP in 0.9% Sodium Chloride Injection USP is 317 mOsmol/L. Each mL provides 0.285 mg (3mM) of phosphate, 0.157 mEq of sodium and 0.154 mEq of chloride. When used according to the preparation instructions (see Dosage and Administration), Methylene Blue Sodium Phosphates/Sodium Chloride mixture act as a stabilizer.

INDICATIONS AND USAGE

Technetium Tc99m exametazime scintigraphy (with or without methylene blue stabilization) may be useful as an adjunct in the detection of altered regional cerebral perfusion in stroke.

Tc99m exametazime without methylene blue stabilization is indicated for leucocyte labeled scintigraphy as an adjunct in the localization of intra-abdominal infection and inflammatory bowel disease.

CONTRAINDICATIONS

None known.

PRECAUTIONS

As with any injected product, acute hypersensitivity or allergic reactions are possible. Limited reports have been received of hypersensitivity reactions following administration of Tc99m labeled leukocytes prepared using Tc99m exametazime. However, the materials used in leucocyte cell separation may cause hypersensitivity reactions. It is essential that cells are washed free of sedimentation agents before they are reinjected into the patient.

In case of side effects following administration of radiopharmaceuticals, users should ensure the availability of appropriate medical treatment at the time of administration of any radiopharmaceutical to the patient.

A thorough knowledge of the normal distribution of intravenously administered technetium Tc99m exametazime injection is essential in order to interpret pathologic studies accurately. Caution should be exercised in making the final diagnosis. Results can be affected by the presence of tumor, infarction, peritonitis, non-gastrointestinal or bony sites of inflammatory cell collections.

The contents of the Ceretec vial are not radioactive. After the sodium pertechnetate Tc99m is added, the product is radioactive and adequate shielding of the final preparation must be maintained. The contents of the Ceretec vial are intended only for use in preparation of technetium Tc99m exametazime injection and are NOT to be administered directly to the patient.

General

The contents of the Ceretec vial are sterile and pyrogen free. The vial contains no bact eriostatic preservative. It is essential that the user follow the directions carefully and adhere to strict aseptic procedures during preparation of the radiopharmaceutical.

Radiopharmaceuticals should be used only by or under the control of physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

To minimize radiation dose to the bladder, the patient should be encouraged to void when the examination is completed and as often thereafter as possible. Adequate hydration should be encouraged to permit frequent voiding.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term animal studies have not been performed to evaluate carcinogenic potential or whether exametazime affects fertility in males or females. When evaluated in the Ames test, exametazime increased the apparent rate of gene mutation in the TA100 strain of S. typhimurium. Exametazime did not cause chromosomal aberrations in vitro (Chinese Hamster Ovary cells) or in vivo (rat bone marrow).

Pregnancy Category C

Animal reproduction studies have not been conducted with Tc 99m exametazime. It is also not known whether Tc99m exametazime can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity. Therefore, Tc99m exametazime should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Technetium Tc99m is excreted in human milk during lactation. It is not known whether exametazime is excreted in human milk. Therefore, formula feedings should be substituted for breast feeding for sixty hours.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Rash with generalized erythema, facial edema and fever has been reported in less than 1% of patients. A transient increase in blood pressure was seen in 8% of patients.

Cautionary Notes

1) 0.37 GBq up to 2.00 GBq (10 mCi up to 54 mCi) technetium Tc99m may be added to the vial. Before reconstitution the technetium Tc99m generator eluate may be adjusted to the correct radioactive concentration to a volume of 5 mL by dilution with preservative-free, non-bacteriostatic saline for injection.

2) **Use only eluate from a technetium Tc99m generator which was previously eluted within 24 hours. For brain imaging when using stabilizing protocol, generator eluate more than 30 minutes old should not be used. For the highest radiochemical purity reconstitute with freshly eluted technetium Tc99m generator eluate. For white blood cell labeling, generator eluate more than 2 hours old should not be used.**

3) Radiochemical purity testing must be performed prior to patient administration. A radiochemical purity greater than 80% is necessary for product acceptance.

4) Do not use the final radiopharmaceutical preparation for Ceretec with Methylene Blue stabilizer more than 4 hours after the time of reconstitution. Do not use the final radiopharmaceutical preparation for Ceretec without Methylene Blue stabilizer more than 30 minutes after the time of reconstitution. Discard any unused material.

HOW SUPPLIED

The kit comprises five individual vials of sterile, non-pyrogenic, freeze-dried mixture of exametazime, stannous chloride dihydrate and sodium chloride, ten radiation labels, six sterile alcohol swabs, five radiochemical purity worksheets, five labeling efficiency worksheets, one package insert, five individual vials of Methylene Blue Injection USP 1%, five individual vials of 0.003 M Monobasic Sodium Phosphate USP and Dibasic Sodium Phosphate USP in 0.9% Sodium Chloride Injection USP and fifteen 0.45 µM syringe filters.

Caution: Federal (U.S.A.) law prohibits dispensing without prescription.

This reagent kit is approved for use by persons licensed by the Illinois Department of Nuclear Safety pursuant to 32 Ill. Code Adm. Section, Section 330.260(a) and 335.4010 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, or an Agreement State.

Patent No. 4,789,736

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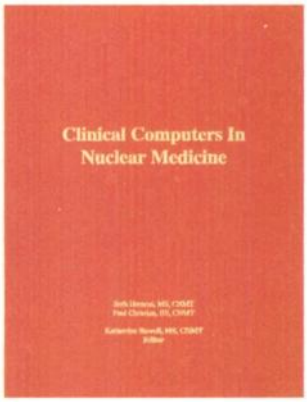

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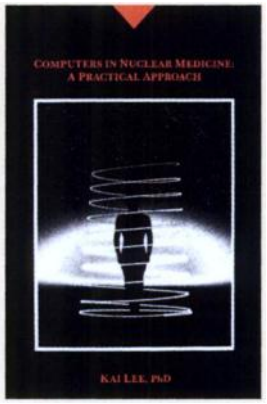

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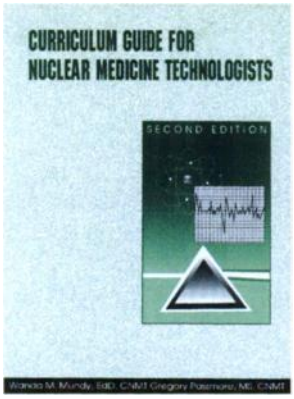

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April 1995

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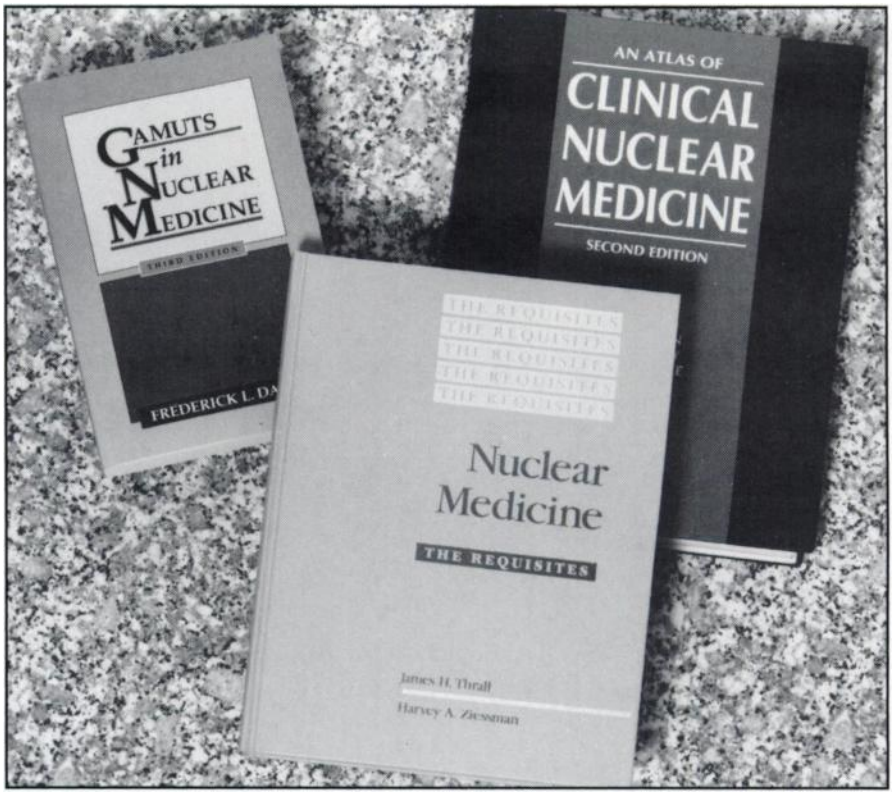

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Henry H. Kramer, Ph.D., FACNP
Executive Director

April 17, 1995

Dear Valued Customers:

During the week of April 10th, there were questions regarding the supply of molybdenum/technetium in the United States. We are very pleased to tell you that no supply problems occurred. The Council on Radionuclides and Radiopharmaceuticals (CORAR) has initiated a collaborative effort on behalf of its members—DuPont Radiopharmaceuticals, Mallinckrodt Medical, Inc., Medi-Physics Inc., Amersham Healthcare, and Nordion International—to address these questions and ensure adequate supply of this essential product.

The manufacturers' number one priority is to provide customers with the highest level of service, ensuring quality patient care now and in the future.

Late last week, Nordion communicated that the NRU reactor in Chalk River, Canada, experienced a production problem. Nordion informed CORAR that the mechanical system at the AECL/Nordion production reactor jammed, requiring that the reactor be shut down in order to allow personnel to service the equipment safely. Fortunately, the repairs were made and operations promptly resumed.

To provide consistent service, Nordion promptly secured an alternate source of molybdenum in Europe. In addition, CORAR contacted and worked closely with the Food and Drug Administration, as well as the Nuclear Regulatory Commission. The responsiveness of these agencies assured CORAR that the alternate material would satisfy US regulatory standards. If molybdenum production at AECL/Nordion *had* been interrupted, this alternate source would have been available to help fill demand for molybdenum in the United States, thereby minimizing any impact on patient care.

Again, we are pleased that you did not experience any inconvenience or disruption in molybdenum/technetium shipments. Be certain CORAR is working to provide continued reliability, utilizing several reactors to help prevent any lapse in the supply of molybdenum in the United States. If you have any questions, please contact your supplier directly at the numbers listed below.

Sincerely,
Carl Seidel, Chairman
The Council on Radionuclides and Radiopharmaceuticals*

Carl Seidel
DuPont Radiopharmaceuticals
(800) 343-7851

Roy Brown
Mallinckrodt Medical, Inc.
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Bill Ehmig (ext. 244)
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*The Council on Radionuclides and Radiopharmaceuticals, Inc., is an association of companies with common interests in radionuclides, radiochemicals, and other radioactive products primarily used in medicine, life science research, and radiopharmaceuticals. The member companies of CORAR represent the major manufacturers of radiopharmaceuticals in the United States.

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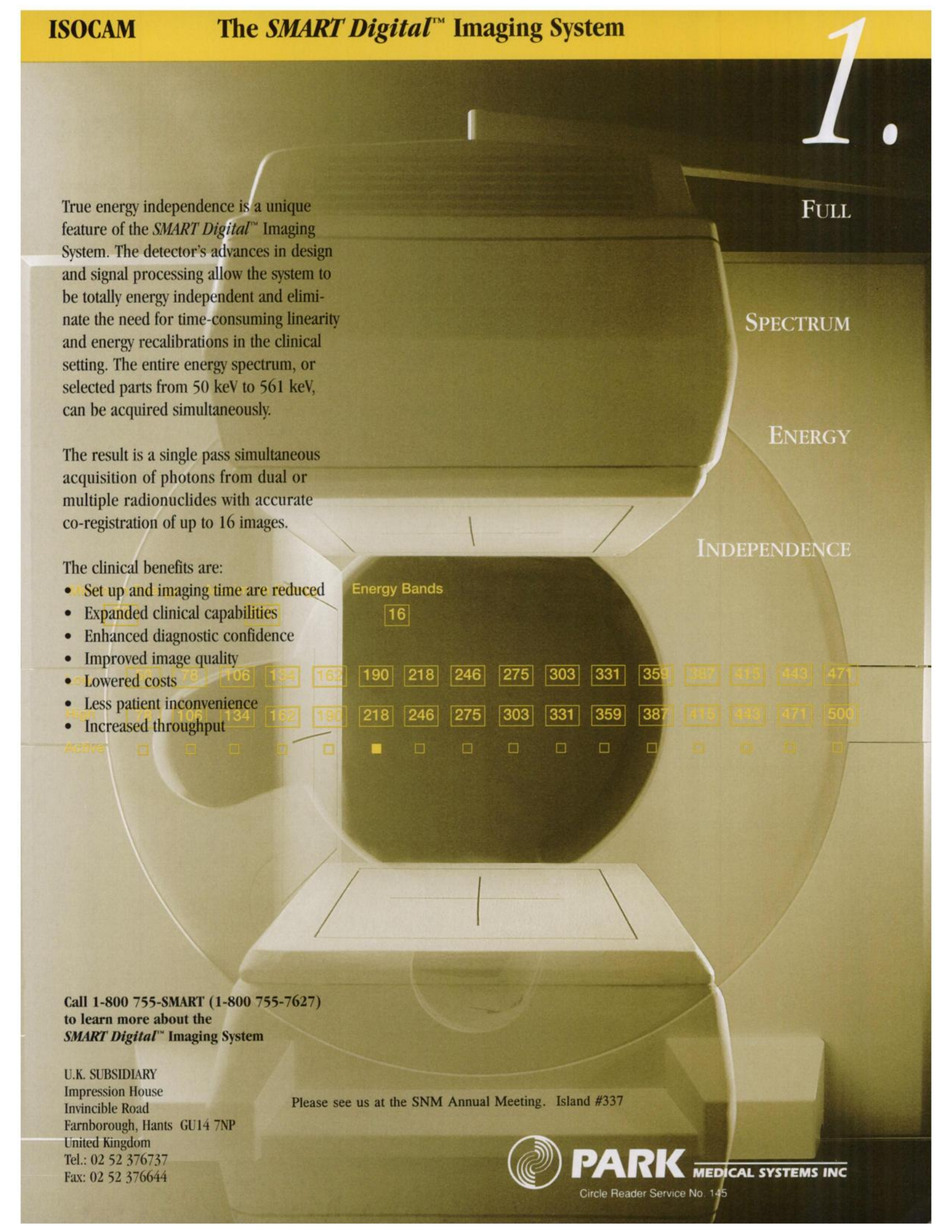

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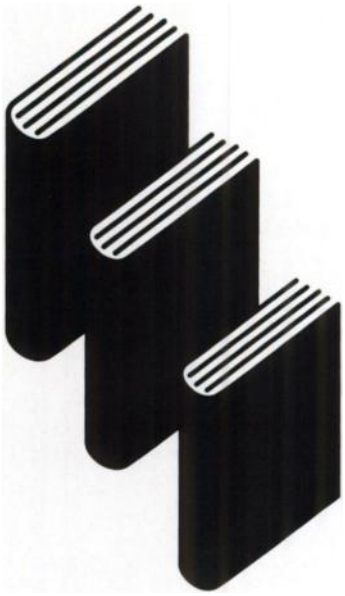

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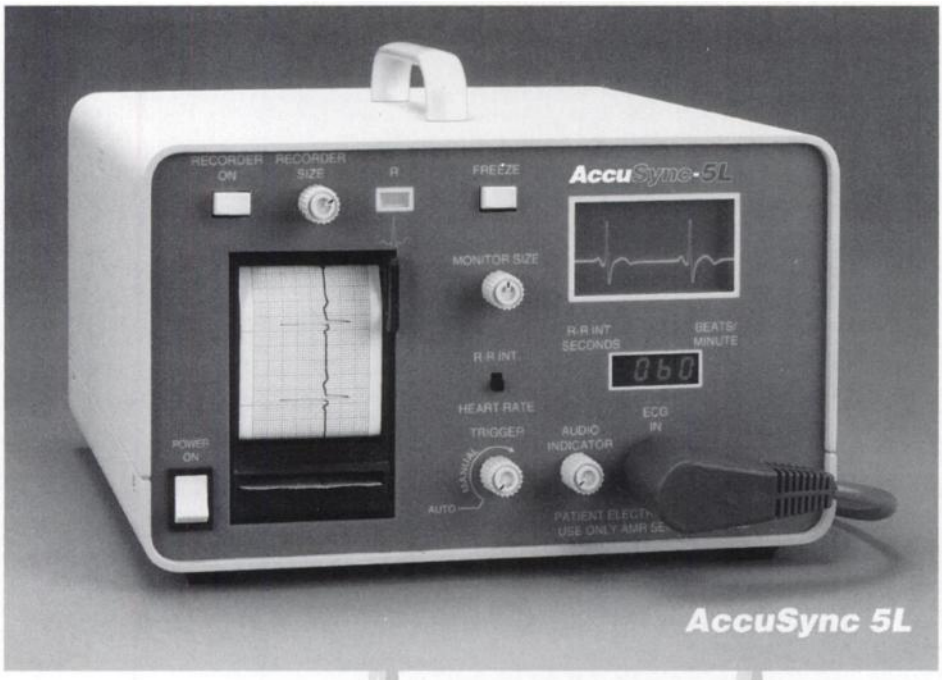

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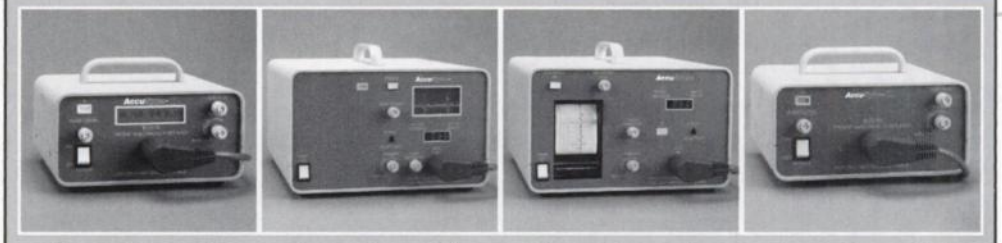

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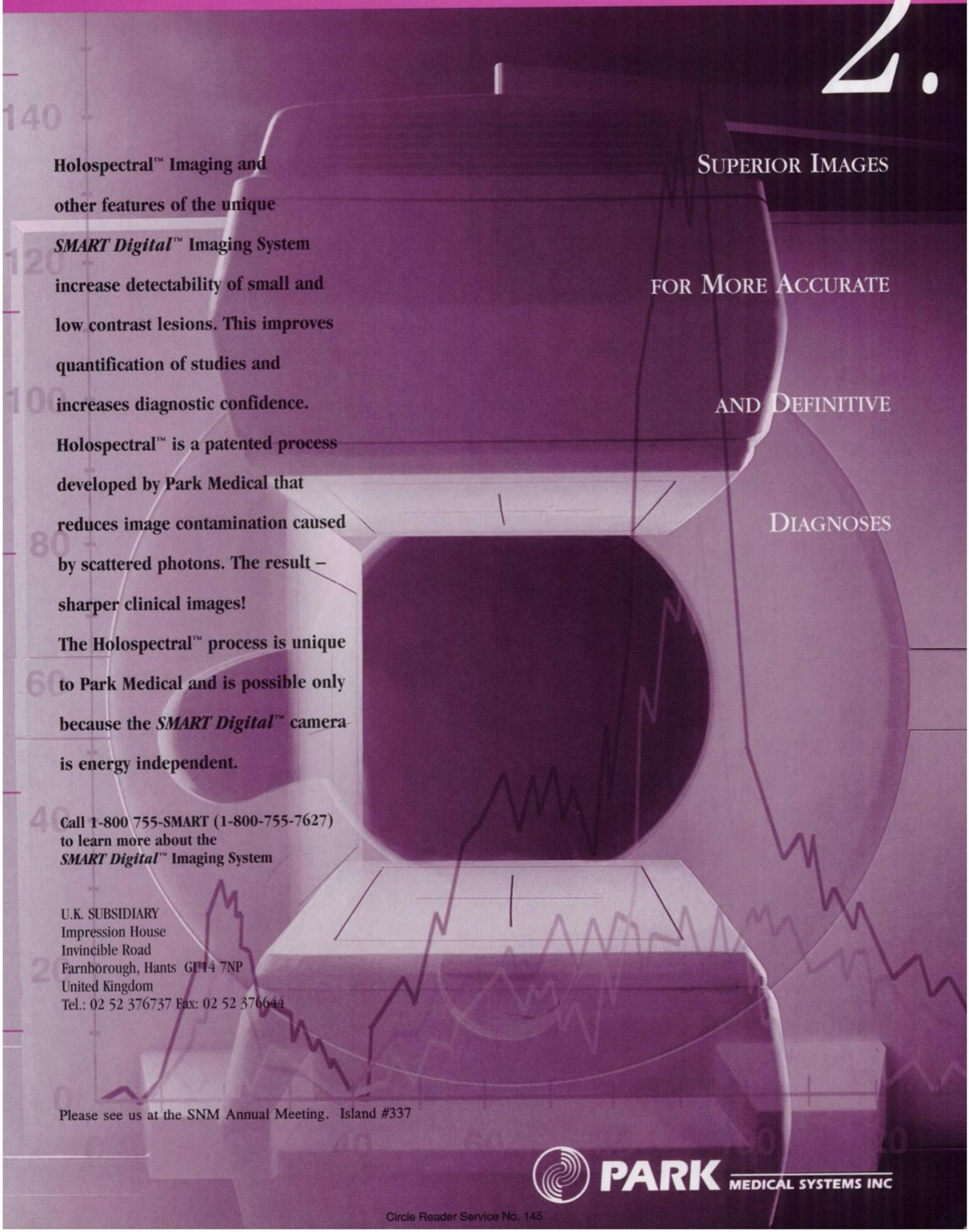

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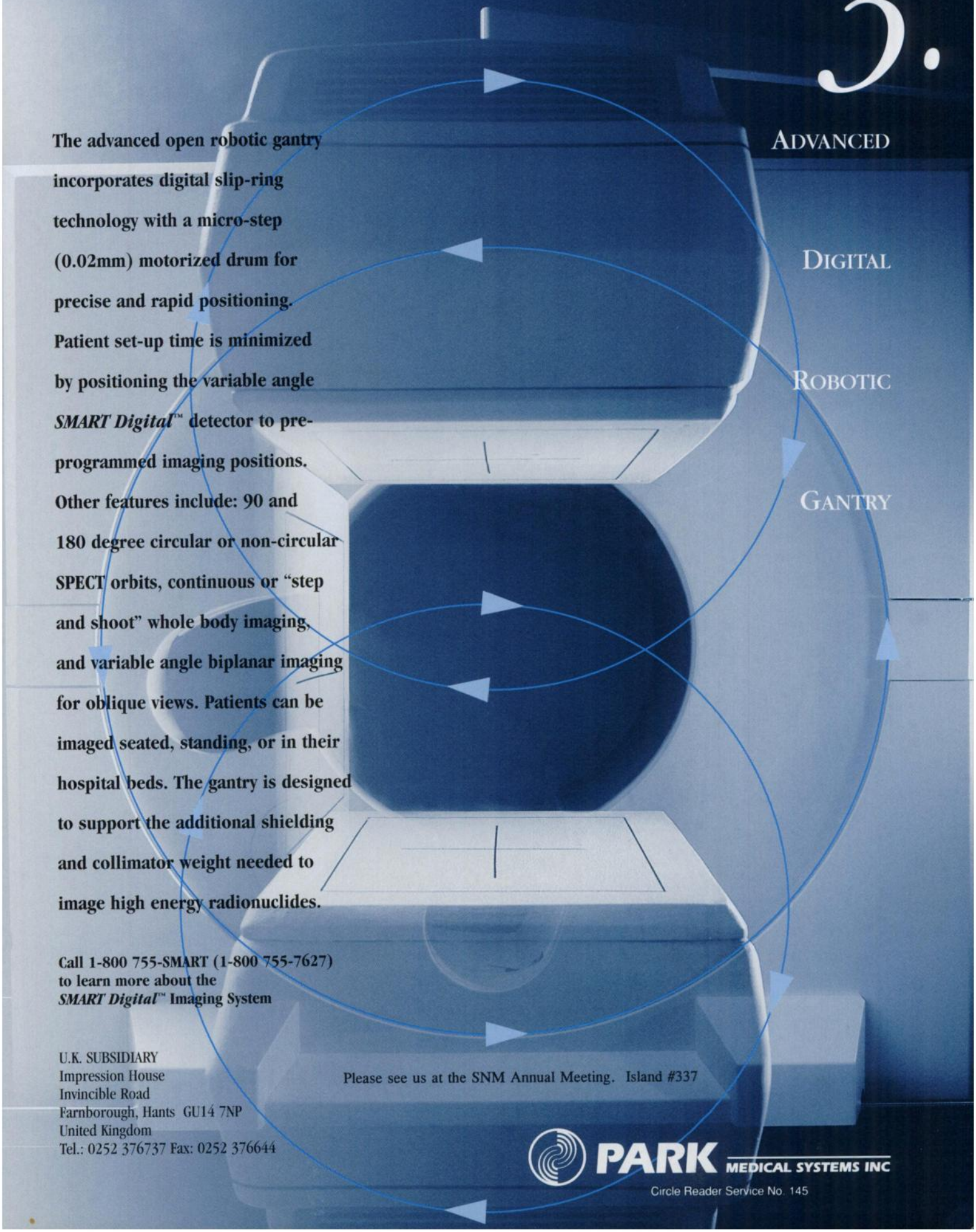

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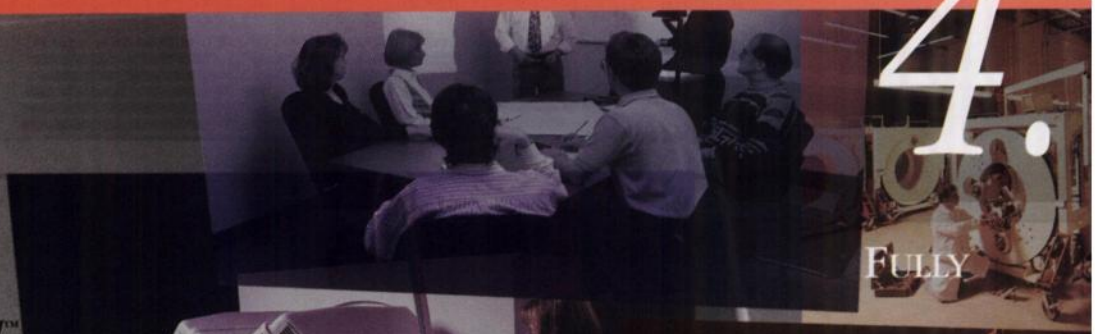

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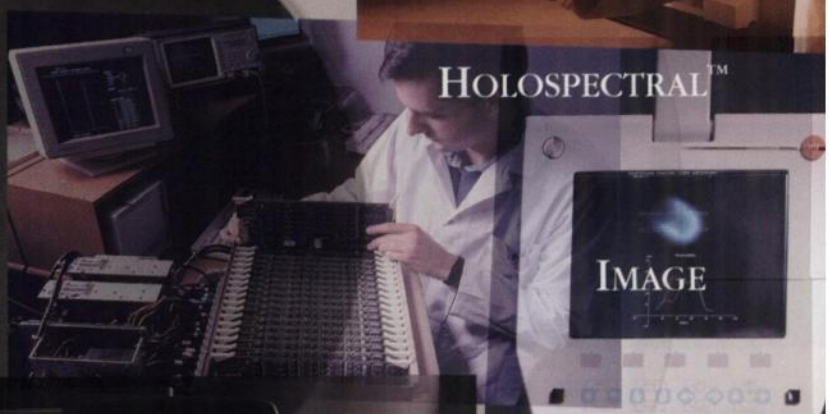
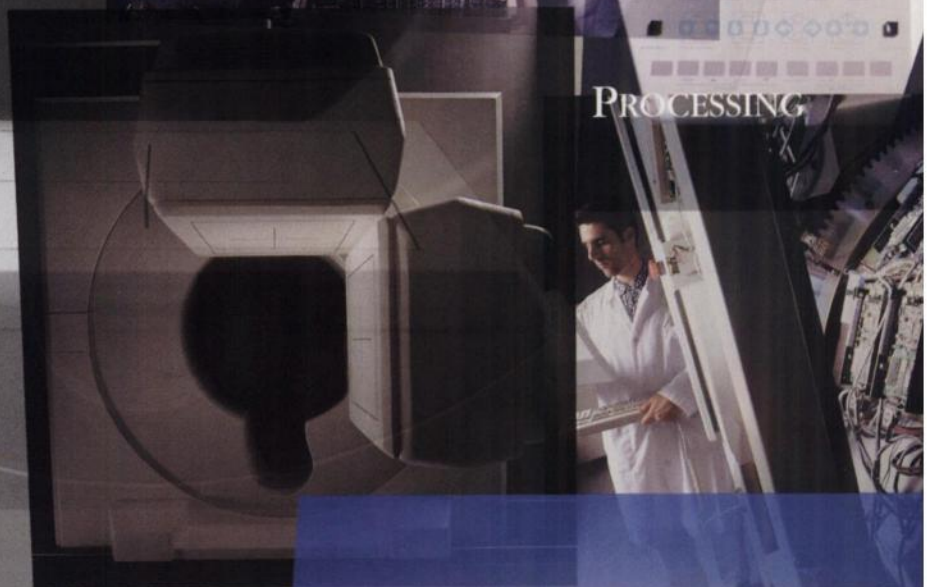


HOLOSPECTRAL™

IMAGE



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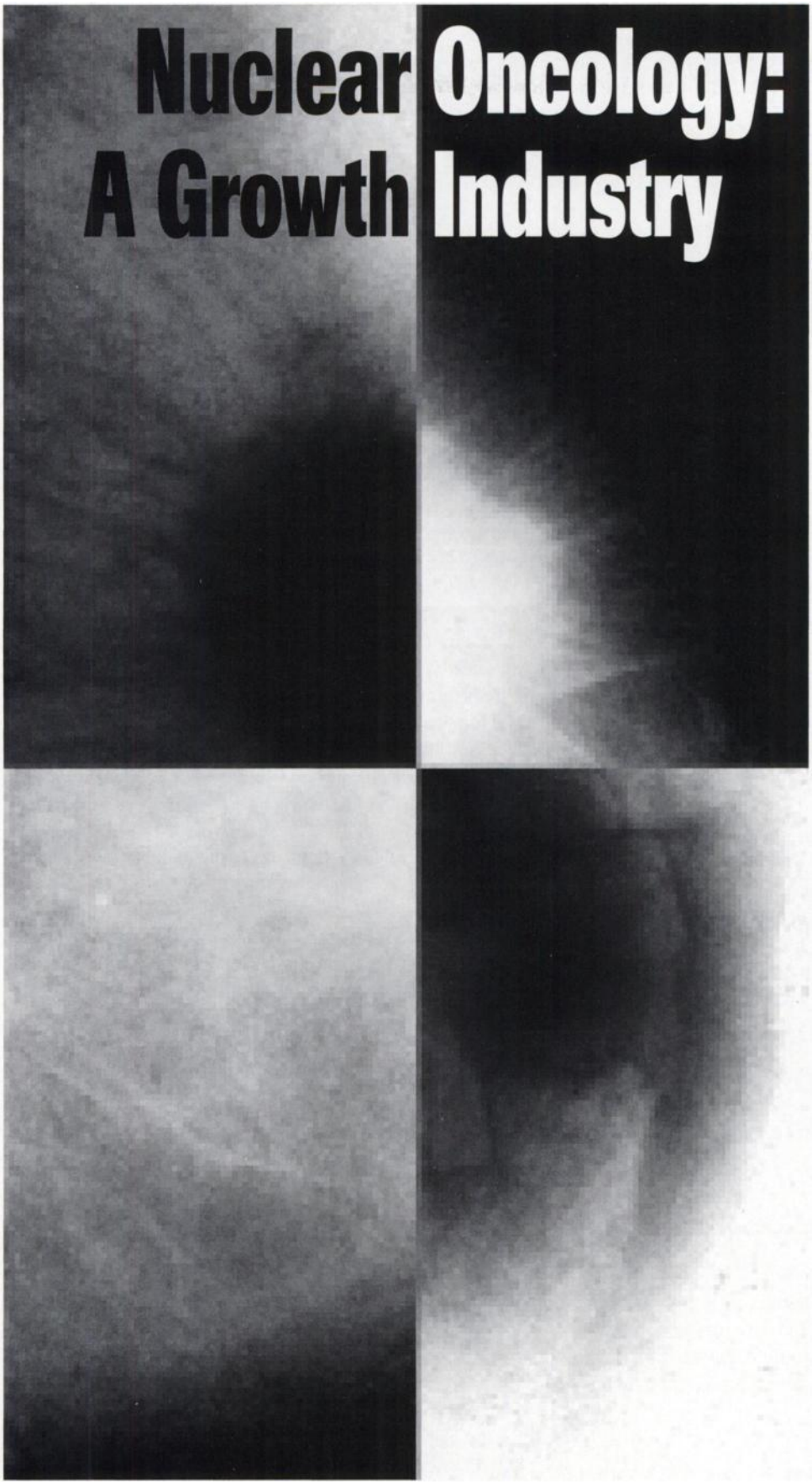
PARK MEDICAL SYSTEMS INC

Nuclear Oncology: A Growth Industry



THE GROWTH AND IMPACT OF NUCLEAR ONCOLOGY IS THE FOCUS OF THIS ISSUE OF THE JOURNAL. IT IS DEDICATED TO CLINICAL AND BASIC STUDIES INVOLVING RADIONUCLIDES, RADIOLABELED ANTIBODIES AND SOMOSTATIN ANALOGS IN DIAGNOSTIC AND THERAPEUTIC APPLICATIONS.

SIGNIFICANT GROWTH HAS OCCURRED IN THIS AREA DURING THE LAST FEW YEARS, FURTHER VALIDATING THE CLINICAL EFFICACY OF DIAGNOSTIC IMAGING PROCEDURES, A CONTRAST TO THE CURRENT HEALTHCARE ENVIRONMENT.

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THE UNIVERSITY OF CALIFORNIA, Davis School of Medicine has a full-time faculty position available in the Nuclear Medicine Division of the Department of Radiology. Appointment will be at the Assistant Professor level (Professor of Clinical Radiology Series). Candidates must be Board certified in nuclear medicine, eligible for licensure in California, and have an academic background in nuclear medicine. Since this position will be Open Until Filled please forward curriculum vitae, a letter outlining background and interests in teaching/research and the names of five references as promptly as possible. This position is Open Until Filled, but no later than June 30, 1995. Reply to: Richard W. Katzberg, MD, Professor and Chairman, Department of Radiology, 2525 Stockton Boulevard, MSF Building, Sacramento, California 95817. The University of California is an Equal Opportunity/Affirmative Action Employer and encourages applications from women and persons of color.

Position Wanted

ABNM and American Board of Pathology (AP/CP) ivy league trained physician is seeking a position. My credentials are impeccable and I have extensive experience in all aspects of nuclear medicine (with strong background in pediatric studies). Please contact David A. Summerville, MD, PhD. at 407-578-9407.

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An opening for a Radiopharmacist exists with the Positron Emission Tomography Department (PETD) of the Clinical Center, National Institutes of Health, Public Health Service in Bethesda, Maryland. The PETD has an active program in radiopharmaceuticals, radiopharmacy, imaging physics, modeling, and data analysis sciences. There are extensive resources available, including two medical cyclotrons, six hot cells and laboratories for radiochemistry, three PET tomographs (two brain units and a whole body instrument), and computer hardware and software for the generation and analysis of physiological images. The radiopharmacist assists in total PETD quality assurance with primary responsibility for quality control of a wide variety of new and established PET radiopharmaceuticals. Applicants must possess a bachelor's degree in pharmacy and be licensed to practice pharmacy. Applicants must also have experience in radiopharmacy and analytical techniques, e.g., HPLC, either through a formal training program or experience in a nuclear medicine department. Salary is commensurate with qualifications. Full benefits coverage is included.

To obtain application materials, contact:

Pam Stevenson, National Institutes of Health,
CC/OHRM/POS, Building 10, Room 1N312
10 Center Drive MSC 1200
Bethesda, MD 20892-0010
Telephone (301) 496-6924; Fax (301) 594-2996

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The position must be filled by a physician. Applicants with certification in internal medicine, psychiatry, neurology, nuclear medicine or related specialties, and demonstrated research and clinical excellence are encouraged to apply to: **"Clinical Director", c/o Personnel, NIH/NIDA/DIR, P.O. Box 5180, Baltimore, Maryland 21224.**

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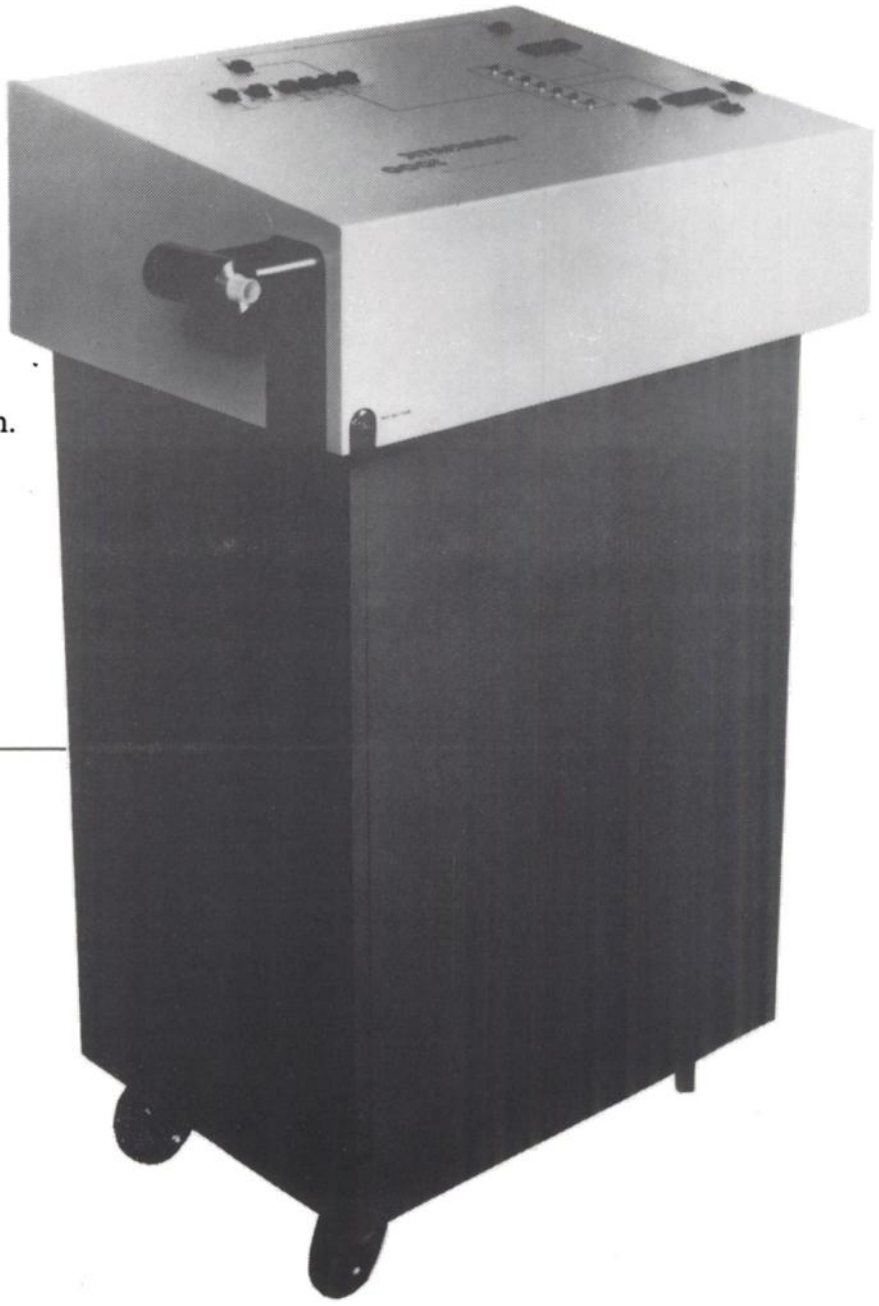

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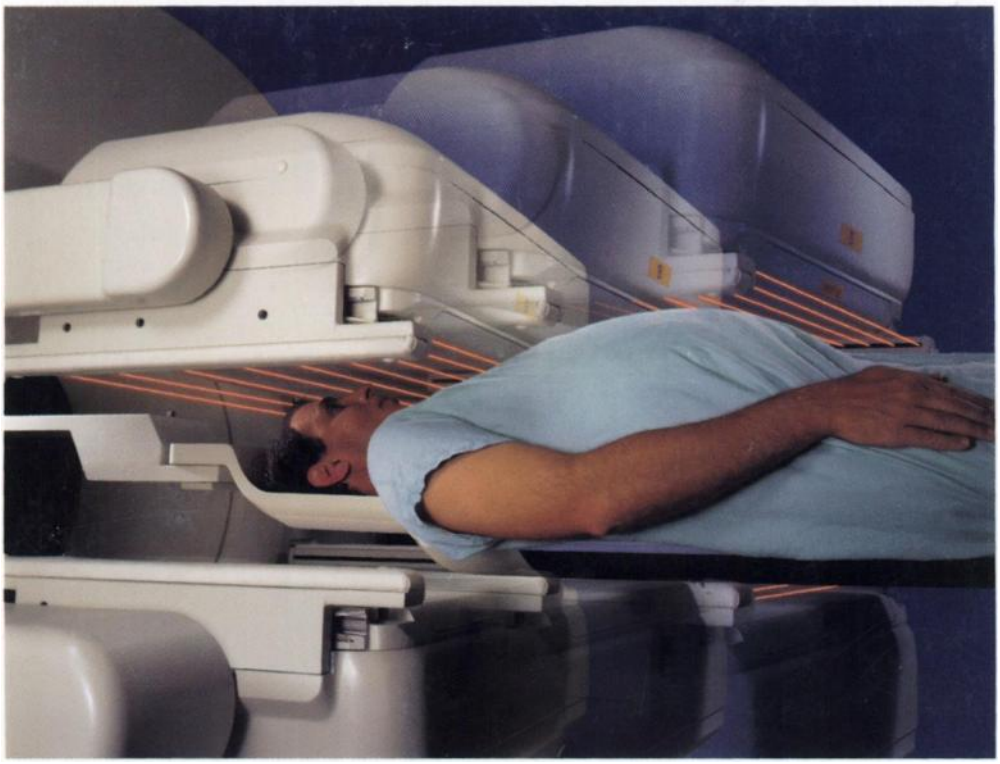

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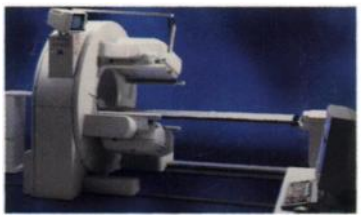

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